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Dialifor (O, O-diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate) Pesticide Registration Standard

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This document contains information regarding reregistration of pesticide products containing 0,0-diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate (Dialifor), including how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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Dialifor

(O, O-diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate)

Pesticide Registration Standard

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DIALIFOR

Pesticide Registration Standard

Denise Keehner	Project Manager (SPRD)
Daniel Byrd	PhD (SPS, HED)
George Beusch	Chemist (RCB, HED)
M. Ferretti	Chemist (RCB, HED)
Lionel Richardson	Environmental Chemist (EFB, HED)
Chad Sandusky	Toxicologist (TOX, HED)
William Rabert	Fish & Wildlife Biologist (EEB, HED)
Robert Holst	Plant Physiologist (EEB, HED)
Mark Dow	Entomologist (ASIB, BFSD)
Kate Devine	Economist (EAB, BFSD)

June, 1981

Office of Pesticides and Toxic Substances

Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

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I

HOW TO REGISTER UNDER A REGISTRATION STANDARD

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Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c) (5) that:

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a 'product by product' basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the 'product by product' approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 2, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements (See FIFRA Section 3(g)).

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the 'product by product' approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishesdocuments called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or re-registration under Section 3(c) (5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c) (1) (B).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c) (5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

Requirement to Re-register Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to re-register allcurrently registered products as expeditiously as possible. Congress also agreed that re-registration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for re-registration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for re-registration set forth in the Guidance Package which accompanies this Standard.

"Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29696, July 10, 1978, and 43 FR 37336, August 22, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in affect for some time and are, the Agency belives, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that is " product specific ," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c) (1) (D)] or data generation [under Section 3(c) (2) (B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he re-registers his product. An applicant for registration of a new product under this Standard may similarly by request approval for only certain use patterns.

Data Compensation Requirements under FIFRA 3(c) (1) (D)

Under FIFRA Section 3(c) (1) (D), an applicant for registration, re-registration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by all the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration.

(3) they are the kind of data which are relevant to the Agency's decision to register or re-register the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

(4) the Agency has found the data to be valid and usable in reaching regulatory conclusions; and

(5) they are not data for which the applicant has been exempted by FIFRA Section 3(c) (2) (D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for re-registration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c) (1) (D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which is specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C) (1) (D) for that data.

Each applicant for registration or re-registration of a manufacturing-use product, and each applicant for registration or re-registration of an end-use product, who is not exempted by FIFRA Section 3(c) (2) (D), must comply with the Section 3(c) (1) (D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for re-registration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c) (2) (B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c) (2) (B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c) (2) (B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in its summary second chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may posses sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the " product specific" data gaps on a 'product by product' basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of re-registering currently registered products, EPA will issue Section 3(c) (2) (B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question is "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c) (2) (B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c) (2) (B).

Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has indentified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

CHAPTER II

AGENCY POSITION ON DIALIFOR

Introduction

This chapter describes in detail the Agency's regulatory position on products which contain dialifor as the sole active ingredient. The regulatory position adopted by the Agency incorporates a number of considerations. Foremost among these considerations is an analysis of the registrability of products containing dialifor based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Agency's determination is presented below, and the rationale for this basic decision follows the position.

In addition to this decision, standards of product composition, acute toxicity, and use are established. The rationale for establishing a particular standard follows the presentation of the standard. Regulatory actions such as establishing farmworker safety (reentry) intervals are prescribed, and additional data are requested. The basis for any regulatory action can be found by first reading the rationale for the action, which follows the chosen regulatory option. Further information, on the scientific basis for an action, can be found by reading the various disciplinary chapters which present summaries of available scientific data on the safety of dialifor.

In general, the basis for establishing a data requirement can be found in the topical discussion portion of a disciplinary chapter. References to Agency guidelines for testing are provided when appropriate.

Description of Chemical

Dialifor is an insecticide used for the control of a variety of mites, spiders and scales on grapes, pecans, citrus and apples. Dialifor is the common name for O,O-Diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate. There is only one currently registered manufacturing-use product.

Dialifor end-use products are marketed under the trade name Torak®. These products are available in emulsifiable concentrate and wettable powder formulations.

Regulatory Position for Products Containing Dialifor

Dialifor (O,O-Diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate) as described in this standard may be registered for sale, distribution, reformulation, and use in the United States. Considering all information available to the Agency from the open literature and provided to the Agency by registrants, as of October 5, 1980, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for pesticide products containing dialifor.

Available data indicate that the use of dialifor will not result in unreasonable adverse effects to man or his environment. Gaps in the data base preclude the completion of the Agency's risk assessment. Currently registered dialifor products may be reregistered subject to the conditions imposed. New products may be registered under this Standard and are subject to the same requirements.

Regulatory Rationale for Dialifor

Dialifor is a phthalophosphate insecticide used for the control of a variety of spiders, mites, and scales on citrus, grapes and pecans. Because of the phthalimido radical in the structure of dialifor, the Agency is concerned about potential teratogenic effects. Thalidomide, responsible for the world-wide increase in the incidence of phocomelia (a shortening or complete absence of the limbs) in the early 1960's, also contained the phthalimido radical. Dialifor's chemical similarity to Thalidomide is discussed in more detail in the Toxicology chapter of this Standard.

The Agency screened three unaudited teratogenicity studies on dialifor completed by Industrial Biotest Laboratories (IBT), and reviewed one study, identified in the open literature, completed by Jane Robens. None of these studies report significant teratogenic or fetotoxic effects. While no definitive conclusions can be reached on the teratogenic and fetotoxic properties of dialifor, two of the IBT studies and the Robens study do suggest that dialifor may cause teratogenic and fetotoxic effects.

Additional testing on the potential teratogenicity of dialifor is required. The species selected for testing is of special concern, because the teratogenic effects of Thalidomide are more reliably reproduced in rabbits. Because dialifor is structurally similar to Thalidomide, there is a good possibility that the mode of action may be similar, and that testing in rabbits would provide more accurate information.

Dialifor, like many organophosphate insecticides, causes acetyl cholinesterase depression. The potential hazards to farmworkers posed by dialifor residues in the agricultural workplace have been the subject of considerable concern over the past decade in the State of California. Concern focused on the existence of the potentially more potent cholinesterase inhibitor dialifor-oxon as a residue in California vineyards, two field worker poisoning incidents (considered to be siginificant by State authorities) and reports of its ineffectiveness as a pesticide.

This concern culminated in the imposition of a 75-day reentry period in California, for the use of dialifor on grapes, by the Department of Food and Agriculture for the State of California. In addition, this Department requested the completion of a reentry study on humans by the manufacturer. Available data indicate that such a study was never completed. Communication with the California Department of Food and Agriculture indicated that the registrant subsequently submitted a voluntary cancellation for this use pattern in California.

The Department of Food and Agriculture for the State of California was also concerned about residue levels in treated commodities at the time of harvest. This Department expressed some concern that residue levels, although within Federal tolerance limits, were too high given the toxicity of dialifor and dialifor-oxon.

Valid safety data available to the Agency is scarce, and the Agency is unable to set a No Observed Effect Level (NOEL) for red blood cell and plasma cholinesterase depression for dialifor or for dialifor-oxon. This precludes the completion of a formal risk assessment. However, the Agency does recognize that dialifor is a cholinesterase inhibitor, and that some regulatory action is warranted based on the existence of reports of accidents involving fieldworkers exposed to weathered residues of dialifor.

The first poisoning incident (1973 in Fowler, California) involved 32 pickers who harvested grapes 42 days after application of dialifor. Workers were exposed to residues of both dialifor and phosalone (another organophosphate insecticide). The second poisoning incident, (September of 1976 in Madera, California) involved 118 grape pickers exposed to residues of dialifor and phosalone. Available information on this incident indicates that reentry occurred approximately 15 days following application of dialifor.

Data summarized in the Environmental Fate and Residue Chemistry Chapters indicate that the oxygen analog of dialifor is formed by photolysis, and that this metabolite may be present in quantities up to 12.5% of weathered residues on crops (see Residue Chemistry Chapter). Data are not available to quantify the exact amount of dialifor-oxon residues present over time, or to establish the persistence of this metabolite, or dialifor itself, in the field. It is highly likely that the characteristically hot, arid climate of California increases the persistence of this oxon. The possibility of several toxicologically significant chemicals in the weathered residue greatly complicates an analysis of the relationship between application rate, remaining residues, and dose and response.

The foliar residues of dialifor and its oxygen analog are suspected of playing the principal role in farmworker exposure. These residues are dislodged by the activity of the workers, become airborne, and "fall out" over the surface of the worker's clothing and exposed skin. The amount of available foliar residue is influenced by chemical characteristics, crop type, and weather conditions following application.

A reentry study completed in 1980 involving the use of dialifor on grapes supports a farmworker safety interval of at least 65 days for this use in the State of California. The official reentry interval for this use in California is 75 days.

Section 3(c)8 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) directs the Agency not to initiate a Rebuttable Presumption Against Registration action unless the action is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse effects to man or the environment. Available data do not indicate that the use of dialifor will result in unreasonable adverse effects. However, numerous gaps in the data base preclude the completion of quantitative risk assessments.

In the interim, pending receipt of data to complete the risk assessment, the Agency has decided to adopt the 75-day reentry interval imposed by the Department of Food and Agriculture for the State of California for the use of dialifor on grapes, as a federally accepted farmworker safety interval for this use pattern. Data, to establish safe reentry intervals for other registered crops, are being requested.

Data to determine acceptable reentry intervals for the use of dialifor on citrus, pecans, and apples do not exist, and available reentry data on grapes cannot be extrapolated to other use patterns.

Preharvest intervals have been reviewed and have been found to be adequate to insure residue levels in raw agricultural commodities below tolerance limits at harvest. A full battery of acute, subchronic, and chronic toxicity testing is requested on dialifor, as well as acute oral and acute dermal toxicity testing of dialifor-oxon. These toxicology data, when submitted, will be used to reassess current tolerance limits.

If dialifor-oxon is found to be significantly more toxic than dialifor, an analytical method (of appropriate sensitivity as determined from toxicity data) and a full compliment of crop residue data specific to the oxon will be required.

Data available to the Agency indicate that dialifor is applied to less than 1% of registered crops. The Agency is, however, very concerned about potential hazards to the general population (through ingestion of dialifor treated crops), to applicators (through spray application of liquid formulations), and to farmworkers (through harvesting of dialifor treated crops) exposed to this pesticide. Available data suggest a high acute toxicity and a potential for inducing teratogenic effects.

Because of these and other toxicological considerations, the Agency is requiring a full battery of acute, subchronic, and chronic testing, as well as data on fish and wildlife effects and fate of this pesticide in the environment.

Criteria for Registration Under this Standard

To be subject to this Standard, dialifor products must:

1. contain dialifor as the sole active ingredient;
2. be within acceptable standards of composition;
3. be within acceptable acute toxicity limits;
4. be labeled for acceptable end-uses; and
5. bear required labeling.

Manufacturing-use dialifor products must bear label directions for formulation into acceptable end-uses.

Applicants for registration or reregistration of dialifor products under this Standard must comply with all terms and conditions described in the following sections, including commitment to fill data gaps on a time schedule specified by the Agency and when applicable offer to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). As discussed in Chapter I, applicants for the registration of dialifor products under this Standard must contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

A. Manufacturing-use Dialifor

1. Acceptable Ranges and Limits

a. Product Composition Standards

The only currently registered manufacturing-use dialifor product contains 90% dialifor. To be covered under this Standard, manufacturing-use dialifor products must contain dialifor as the sole active ingredient. Any percentage of active ingredient is acceptable with appropriate certification of limits.

The Agency has determined that information on the physical/chemical properties of technical grade dialifor cannot be used to fulfill product chemistry requirements for the currently registered manufacturing-use product. Data are required on the physical/chemical properties of both technical grade dialifor and the currently registered manufacturing-use product.

b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use dialifor products which have established acute toxicity category I-IV ratings for each of the following effects:

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation

c. Use Patterns

To be covered under this Standard, manufacturing-use dialifor products must be labeled for formulation into end-use pesticides which are intended for outdoor nondomestic terrestrial applications (food or non food uses).

Dialifor is currently registered for use only in agricultural applications. Tolerances have been established for dialifor use on grapes, citrus, apples and pecans. Tolerances have also been established for residues of dialifor in meat (red), milk, poultry, and eggs.

The Agency will consider additional tolerances on food or feed crops provided that applicants for the registration of the additional crop(s) submit a petition(s) proposing a tolerance level for each crop, supply appropriate residue data, and demonstrate that the addition of the tolerance will not result in an unacceptable risk to the general population. Applicants must also demonstrate that the additional food-use pattern(s) will not result in an unacceptable risk to applicators or to fieldworkers.

The Agency will also consider non-food (non domestic) terrestrial outdoor uses of dialifor provided any additional required data are submitted for the registration of the use and provided the use pattern will not result in an unacceptable risk to applicators.

Dialifor cannot be registered for (general) domestic use under this standard because of potent cholinesterase inhibiting properties, and high dermal toxicity (Category II) of currently registered end-use products. The application of dialifor involves the mixing and spraying of liquid formulation upwards onto the foliage of apples, citrus, grapes, and pecans. Application is made, in some cases, until the crop is soaked and dripping with dialifor. The homeowner-applicator cannot be reasonably expected to exert the effort needed to eliminate the possibility of exposure to potentially toxic quantities of dialifor by the dermal route as a result of application.

2. Required Labeling

All manufacturing-use dialifor products must bear appropriate labeling as specified in 40 CFR 162.10.

3. Tolerance Reassessment

Tolerances have been established for combined residues of dialifor and its oxygen analog in or on raw agricultural commodities as indicated: 1.5 ppm in or on apples, 3 ppm in or on citrus fruits, 1 ppm in or on grapes, .01 ppm in or on pecans, .15 ppm in meat, fat, and meat byproducts of cattle, goats and sheep, .15 ppm in milk fat, .05 ppm in meat, fat, and meat byproducts of poultry, and .01 ppm in eggs (40 CFR 180.326).

The theoretical maximum residue contribution (TMRC) of dialifor to the human diet is calculated to be .265 mg/day. This figure is based on average adult eating patterns and on the assumption that each commodity contains residues which meet the established tolerance level.

The Agency is unable to set a No Observed Effect Level (NOEL) for dialifor or for dialifor-oxon. Thus, tolerance levels cannot be reassessed at this time.

B. Emulsifiable Concentrate Dialifor

1. Acceptable Ranges and Limits

a. Product Composition Standards

Currently registered dialifor emulsifiable concentrate products include three products containing 4 pounds per gallon of dialifor. The Agency has determined that existing emulsifiable concentrate products are substantially similar.

Emulsifiable concentrate dialifor products containing up to 50% active ingredient are acceptable (with appropriate certification of limits), as long as application rates (on a per acre basis) remain the same.

The Agency has placed this upper limit on the percentage of active ingredient because available acute dermal toxicity testing of the manufacturing-use product (containing 90% active ingredient) suggests high toxicity. Available acute dermal toxicity testing of the 50% wettable powder product indicates that this product falls into Category II which is acceptable for general, non domestic use.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001.

b. Acute Toxicity Limits

To be registered for nondomestic use under this Standard, an emulsifiable concentrate dialifor product must have an (a):

Acute Oral Toxicity of Category I-IV;
Acute Dermal Toxicity of Category II-IV;
Acute Inhalation Toxicity of Category I-IV;
Primary Eye Irritation of Category II-IV; and
Primary Dermal Irritation of Category II-IV.

Rationale: Emulsifiable Concentrate products with acute oral LD50 values in Category I are acceptable for general use under this Standard. The Agency has determined that appropriate label warnings (against consumption of food and smoking during application and prior to the washing of hands and face following application) will significantly decrease the possibility of ingesting fatal quantities of dialifor. In addition, under normal use conditions, it is unlikely that applicators will be orally exposed to fatal quantities of dialifor.

Emulsifiable Concentrate products with acute inhalation LC50 values in Category I are also acceptable for general use under this Standard. The Agency has determined that labeling (in accordance with 40 CFR 162.10) and formulation type (liquid) can be reasonably expected to eliminate the possibility of the inhalation of fatal quantities of dialifor.

c. Use Patterns and Application Methods

To be registered under this Standard, emulsifiable concentrate products of dialifor may only be used nondomestically, as insecticide-acaricides on apples, citrus, grapes and pecans.

Reentry Intervals

The Agency has accepted the California State reentry interval of 75 days (the longest existing State reentry interval) for the use of emulsifiable concentrate dialifor products on grapes when applied at an application rate of 1 pound dialifor (or less) per acre. This is an interim measure, pending the completion and implementation of Agency reentry guidelines. A reassessment of this interval may become necessary following the completion of the Agency's reentry guidelines.

Registrants of emulsifiable concentrate dialifor products have the option of accepting the California reentry interval of 75 days for the use of dialifor on grapes, or of petitioning for relief based upon local exposure and residue data.

Federally recommended reentry intervals for the use of dialifor on apples, citrus, and pecans cannot be established at this time due to extensive gaps in the data base, and the inability to extrapolate data on grapes to other crops. Data to establish safe reentry intervals for these other crops are required. Reentry intervals may need to be reassessed following the completion of Agency reentry guidelines.

Preharvest Intervals

Preharvest intervals for the use of dialifor on apples, grapes, citrus, raisins, and pecans remain in effect. These intervals have been reassessed and appear to be adequate to insure residue levels in raw agricultural commodities below tolerance limits at harvest. The currently recommended preharvest intervals are as follows:

Crop	Preharvest Interval
Citrus	7 days
Grapes	35 days*
Apples	60 days
Raisins	70 days

* NOTE: Although the current preharvest interval for the use of dialifor on grapes is sufficient to insure residue levels below tolerance limits at harvest, because of worker safety concerns, reentry into treated fields is prohibited within 75 days of application. Registrants have the option of accepting this restriction or of petitioning for relief based upon local exposure and residue data.

Application Rates

The Agency finds that it must limit application rates to current levels. This is an interim measure which may need to be reassessed following the receipt of required data to complete the Agency's risk assessment. Available residue data indicate that application rates cannot exceed: 1.0 pound per acre on grapes, 2.0 pounds per acre on pecans, 2.25 pounds per acre on apples, and 5.0 pounds per acre on citrus, at current preharvest intervals.

Most applicators are certified or work under the supervision of certified applicators. However, the use of dialifor is not restricted to certified applicators or to supervision by certified applicators at this time.

Additional Uses

The addition of similar crops, ie. within the same crop groupings, as registered uses would be considered under this standard provided petitions proposing tolerances, required residue data, safety data, use information, and reentry studies are submitted and found to be acceptable.

Group	Commodities therein
Citrus fruits	Citrus citron, grapefruit, kumquats, lemons, limes, oranges, tangelos, tangerines, and hybrids of these.
Small fruits	Blackberries, blueberries, boysenberries, cranberries, currants, dewberries, elderberries, gooseberries, grapes, hickleberries, loganberries, strawberries, youngberries, and rasberries.
Pome fruits	Apples, crabapples, pears, and quinces.
Nuts	Almonds, Brazil nuts, bush nuts, butternuts, cashews, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pecans, and walnuts.

Emulsifiable concentrate dialifor cannot be registered for (general) domestic use under this standard because of potent cholinesterase inhibiting properties and acute dermal toxicity in Category II (see Toxicology Chapter). The application of dialifor involves the mixing and spraying of a liquid formulation upwards onto the foliage of apples, grapes, citrus, and pecans. Application is made, in some cases, until the crop is soaked and dripping with dialifor. The homeowner-applicator cannot be expected to exert the effort needed to eliminate the possibility of exposure to potentially toxic quantities of dialifor during application.

2. Required Labeling

All emulsifiable concentrate dialifor products must bear appropriate labeling as specified in 40 CFR 162.10.

Reentry

All emulsifiable concentrate dialifor products intended for application on grapes must include the following precaution:

> "Reentry into treated fields is prohibited within 75 days of application."

All labels and labeling intended for agricultural use products must bear the following statement: "This product must be applied in accordance with 40 CFR Part 170." Registrants may state the contents of 40 CFR Part 170 or additional statements.

Additional Restrictions and Precautionary Statements

In addition, emulsifiable concentrate products must bear the following restriction:

> "Not for use or storage in or around the home"

All labels and labeling for emulsifiable concentrate products must bear the following (or equivalent) statements:

> "Do not eat or smoke during exposure. Wash hands and face before eating or smoking"

All labels and labeling for emulsifiable concentrate products must bear the following statement:

> "Do not apply directly to water"

C. Wettable Powder Dialifor

1. Acceptable Ranges and Limits

a. Product Composition Standards

The currently registered dialifor wettable powder product contains 50% dialifor as the active ingredient. Wettable powder dialifor products containing up to 50% active ingredient are acceptable (with appropriate certification of limits), as long as application rates (on a per acre basis) remain the same.

The Agency has placed this upper limit on the percentage of active ingredient because available acute dermal toxicity testing of the manufacturing-use product suggests that this product (containing 90% active ingredient) is very toxic. Acute dermal toxicity testing of the currently registered wettable powder product places this product in Category II, which is acceptable for general, non domestic use.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001.

b. Acute Toxicity Limits

To be registered for nondomestic use under this Standard, a wettable powder dialifor product must have an (a):

Acute Oral Toxicity of Category I-IV;
Acute Dermal Toxicity of Category II-IV;
Acute Inhalation Toxicity of Category I-IV;
Primary Eye Irritation of Category I-IV; and
Primary Dermal Irritation of Category I-IV.

Rationale: Wettable Powder products with acute oral LD50 values in Category I are acceptable for general use under this Standard. The Agency has determined that appropriate label warnings (i.e. against the consumption of food and smoking during during application and prior to the washing of hands and face following application) will significantly decrease the possibility of ingestion of fatal quantities of dialifor. In addition, under use conditions, it is unlikely that applicators will be orally exposed to fatal quantities of dialifor.

Wettable Powder products with acute inhalation toxicity values in Category I are also acceptable for general use under this Standard. The Agency has determined that labeling (in accordance with 40 CFR 162.10) and formulation type (liquid) can reasonably be expected to eliminate the possibility of exposure to fatal quantities of dialifor.

c. Use Patterns and Application Methods

To be registered under this Standard, wettable powder products of dialifor may only be used nondomestically, as insecticide-acaracides on apples.

Wettable powder dialifor is currently registered for use on apples.

Reentry Intervals

Federally accepted reentry intervals for the use of wettable powder dialifor on apples cannot be established at this time due to extensive gaps in the data base. Reentry data on the use of dialifor on grapes cannot be extrapolated to other use patterns.

Preharvest Intervals

The current preharvest interval of 60 days for the use of wettable powder dialifor on apples remains in effect.

Application Rates

The Agency finds that it must limit application rates to current levels. This is an interim measure which may need to be reassessed following the submission of required data to complete the risk assessment. Available residue data indicate that the application rate cannot exceed 2.25 pounds per acre on apples.

Additional Uses

The addition of grapes, citrus, and pecans (and other crops within the same crop groupings, see page 2-9), as registered use patterns for wettable powder dialifor products would be considered under this Standard provided petitions proposing tolerances, required residue chemistry data, safety data, use information, and reentry studies are submitted, and found to be acceptable.

Because the amount of available dislodgeable residues is influenced by formulation type, the reentry interval for the use of emulsifiable concentrate dialifor on grapes is not directly applicable to wettable powder formulations. Additional data are required.

Wettable powder dialifor cannot be registered for (general) domestic use under this Standard because of cholinesterase inhibiting properties, and acute dermal toxicity in Category II (see Toxicology Chapter). The application of dialifor involves the mixing and spraying of a liquid formulation upwards onto the foliage of grapes, apples, citrus, and pecans. Application is made, in some cases, until the crop is soaked and dripping with dialifor. The homeowner-applicator cannot be expected to exert the effort needed to eliminate the possibility of accidental exposure to potentially toxic quantities of dialifor during application.

2. Required Labeling

All wettable powder dialifor products must bear appropriate labeling as specified in 40 CFR 162.10.

Reentry

All labels and labeling intended for agricultural use products must bear the following statement: "This product must be applied in accordance with 40 CFR Part 170". Registrants may state the contents of 40 CFR Part 170 or additional statements.

All labels and labeling for wettable powder products must bear the following (or equivalent) statements:

> "Do not eat or smoke during exposure. Wash hands and face before eating or smoking"
>
> "Do not apply directly to water"

In addition, wettable powder products must bear the following restriction:

> "Not for use or storage in or around the home"

CHAPTER III

DATA REQUIREMENTS AND DATA GAPS

A. Manufacturing-use Dialifor

The majority of chronic, subchronic, and acute toxicity data on manufacturing-use dialifor were generated by Industrial Biotest Laboratories (IBT). These studies are currently under review in the E.P.A. Laboratory Audit Program.

The Agency's policy in the Registration Standards Program is to review IBT studies for indications of adverse effects resulting from administration of the test substance. Any identified adverse effect data are then discussed in the Standard.

If adverse effects are not identified during the Registration Standard review, these studies are considered invalid for registration purposes. Their status as invalid will continue until they have been validated by registrants and the Agency through the Laboratory Audit Program.

A number of studies have not completed the validation process through the Laboratory Audit Program. Thus, some company submitted toxicology data have been declared invalid for registration purposes. These categories of data are identified in the Standard as data gaps.

Table A, entitled: GENERIC DATA REQUIREMENTS AND DATA GAPS FOR MANUFACTURING-USE DIALIFOR PRODUCTS includes those data that pertain to the properties or effects of dialifor as an active ingredient. Thus, these data are relevant to an evaluation of the risks and benefits of all products containing dialifor. Providing data to fill indicated data gaps is the primary responsibility of the manufacturing-use product registrant(s). Registrants of end-use products which are not exempted by FIFRA Section 3(c)(2)(D) are also responsible for the submission of these data. Applicants for the registration or reregistration of manufacturing-use dialifor products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA 3(c)(1)(D). These data are listed under the column entitled: Bibliographic Citation in this table.

Product Chemistry Data

Certain data on the physical/chemical properties of technical grade dialifor are required for the registration of any manufacturing-use product.

Toxicology Data

For purposes of acute oral and dermal toxicity testing, technical grade dialifor has been determined to be equivalent to the currently registered Manufacturing-use product.

Acute oral and dermal toxicity testing of the oxygen-analog of dialifor is required because data indicate that this degradation product may be present in significant amounts in weathered residues in food and in the field. The Agency must be able to quantify the toxicity of this oxon.

Residue Chemistry Data

A petition proposing a tolerance of 110 ppm in citrus oil is needed.

Pending the receipt of data on the toxicity of dialifor-oxon, a full compliment of residue data (including an analytical method of appropriate sensitivity) on the oxygen analog may be required.

Table B, entitled: PRODUCT SPECIFIC DATA REQUIREMENTS AND DATA GAPS FOR MANUFACTRING-USE DIALIFOR PRODUCTS includes those data that relate only to the properties or effects of a product with a specific composition. Thus, these data are required of each product to characterize the product's particular composition and physical/chemical properties, and to characterize the product's acute toxicity. Providing data to fulfill these data requirements for a particular product is the responsibility of each applicant for the registration or reregistration of a manufacturing-use dialifor product. If the Agency has in its possession product specific data which fulfill a data requirement for a particular product, this is indicated in the guidance package accompanying this Standard.

Applicants for the registration of new manufacturing-use dialifor products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has determined that one or more existing manufacturing-use dialifor products are substantially similar, then this too is indicated. Product specific data need not be acknowledged under FIFRA 3(c)(1)(D) unless the Agency or a registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant(s) of the former product(s) is required to acknowledge reliance on these data.

Product Chemistry Data

Data requirements 163.61-3 through 163.61-7 (product composition data) apply to each proposed or currently registered manufacturing-use product.

Data requirements 163.61-8(7) through 163.61-8(18) (physical/chemical properties data) apply to manufacturing-use products which are not the same as the technical grade of the active ingredient. These data are required on manufacturing-use dialifor.

Toxicology Data

Data requirements 163.81-1 and 163.81-2 (acute oral and dermal toxicity) apply to manufacturing-use products which are not toxicologically equivalent to the technical grade of the active ingredient. Technical grade dialifor has been determined to be equivalent to the currently registered manufacturing-use product.

Data requirements 163.81-3 through 163.81-6 apply to each manufacturing-use product or substantially similar product.

B. Emulsifiable Concentrate Dialifor

The Agency has determined that existing emulsifiable concentrate dialifor products are substantially similar.

Registrants of end-use emulsifiable concentrate dialifor products not exempted by FIFRA Section 3(c)(2)(D) are responsible for the submission of "generic" data described in Table A in section III. A of this chapter, in addition to the product specific data listed in Table C.

Registrants of all end-use emulsifiable concentrate products are advised that if data are not generated to fill generic data requirements for the manufacturing-use product(s), these registrations will be suspended. If continued availability of the manufacturing-use product is desired, these data must be supplied.

Table C, entitled: PRODUCT SPECIFIC DATA REQUIREMENTS AND DATA GAPS FOR EMULSIFIABLE CONCENTRATE PRODUCTS includes those data that relate only to the properties or effects of an emulsifiable concentrate product with a specific composition. Thus, these data are required of each emulsifiable concentrate dialifor end-use product to characterize the product's particular composition, physical/chemical properties, and acute toxicity. Providing data to fulfill these data requirements is the responsibility of each applicant for the registration or reregistration of an emulsifiable concentrate dialifor product.

Applicants for the registration of new emulsifiable concentrate dialifor products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has received acceptable product chemistry and/or acute toxicity data for any existing emulsifiable concentrate dialifor product(s), this is indicated in Table C, and the specific product(s) is identified in the guidance package accompanying this Standard. In addition, in the column entitled: Bibliographic Citation , the Identification Numbers of the acceptable studies are provided. These acceptable data are also summarized in the Topical Discussion sections of this Standard. If the Agency has established that a particular product is substantially similar to another product for which the Agency has received acceptable product chemistry and/or acute toxicity data, then this too is indicated.

Product specific data need not be acknowledged under FIFRA Section 3(c)(1)(D) unless the Agency or a registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant(s) of the former product(s) is required to acknowledge reliance on these data.

C. Wettable Powder Dialifor

Registrants of end-use wettable powder dialifor products not exempted form FIFRA Section 3(c)(2)(D) are responsible for the submission of "generic" data described in Tables A and B in Section III.A of this chapter, in addition to the product specific data listed in Table D.

Registrants of all end-use wettable powder dialifor products are advised that if data are not generated to fill generic data requirements for the manufacturing-use product(s), these registrations will be suspended. If continued availability of the manufacturing-use product is desired, these data must be supplied.

Table D, entitled: PRODUCT SPECIFIC DATA REQUIREMENTS FOR WETTABLE POWDER PRODUCTS includes those data that relate only to the properties or effects of a wettable powder product with a specific composition. Thus, these data are required of each wettable powder dialifor end-use product to characterize the product's particular composition, physical/chemical properties, and acute toxicity. Providing data to fulfill these data requirements is the responsibility of each applicant for the registration or reregistration of a wettable powder dialifor product.

Applicants for the registration of new wettable powder dialifor products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has received acceptable product chemistry and/or acute toxicity data for the existing wettable powder dialifor product(s), this is indicated in Table D, and the specific product(s) is identified in the guidance package accompanying this Standard. In addition, in the column entitled: Bibliographic Citation , identification numbers of the acceptable studies are provided. These acceptable data are also summarized in the Topical Discussion sections of this Standard. If the Agency has established that a particular product is substantially similar to another product for which the Agency has received acceptable product chemistry and/or acute toxicity data, then this too is indicated.

Product specific data need not be acknowledged under FIFRA Section 3(c)(1)(D) unless the Agency or a registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant(s) of the former product(s) is required to acknowledge reliance on these data. There is only one currently registered wettable powder product.

TABLE-A

GENERIC DATA REQUIREMENTS AND DATA GAPS
FOR MANUFACTURING-USE DIALIFOR

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
PRODUCT CHEMISTRY						
163.61-3(b)	Identification	Yes	Tech. Grade*	Yes	Hercules, 1970?, 00001982 Hercules, 1970?, 00001942	No
163.61-8(1)	Color	Yes	Tech. Grade	Yes	Hercules, 1970?, 00001932 Hercules, 1970?, 00001942	No
163.61-8(2)	Odor	Yes	Tech. Grade	No		Yes: 6 months
163.61-8(3)	Melting Point	Yes	Tech. Grade	Yes	Hercules, 1970?, 00001912 Hercules, 1970?, 00001942	No
163.61-8(4)	Solubility	Yes	Tech. Grade	Partial	Hercules, 1970?, 00001982 Hercules, 1970?, 00001942	Yes: 6 months
163.61-8(5)	Stability	Yes	Tech. Grade	No		Yes: 6 months
163.61-8(6)	Octanol/Water Partition Coefficient	Yes	Tech. Grade	No		Yes: 6 months
163.61-8(7)	Physical State	Yes	Tech. Grade	Yes	Hercules, 1970?, 00001982 Hercules, 1970?, 00001942	No
163.61-8(8)	Density or Specific Gravity	Yes	Tech. Grade	No		Yes: 6 months
163.61-8(10)	Vapor Pressure	Yes	Tech. Grade	Yes	Hercules, 1970?, 00001982 Hercules, 1970?, 00001942	No
163.61-8(11)	pH	Yes	Tech. Grade	No		Yes: 6 months

* Technical Grade Dialifor

Data Requirements Current
as of June 1991. Refer to
Guidance Package for Updated
Requirements.

TABLE-A (con)

GENERIC DATA REQUIREMENTS AND DATA GAPS
FOR MANUFACTURING-USE DIALIFOR

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
ENVIRONMENTAL FATE						
163.62-7(b)	Hydrolysis	Yes	Tech. Grade*	No		Yes: 24 months
163.62-7(c)	Photodegradation	Yes	Tech. Grade	Partial[5]	Ford, 1971, 00001956	Yes: 24 months
163.62-8(b)	Aerobic Soil Metabolism	Yes	Tech. Grade	Partial[5]	Hercules, 1968, 00002003	Yes: 24 months
163.62-9(b)	Leaching	Yes[1]	Tech. Grade	Partial[5]	Ford, 1971, 00001953	Yes: 24 months
163.62-9(c)	Volatility	Yes	Tech. Grade	No		Yes: 24 months
163.62-9(d)	Adsorp./Desorp.	Yes	Tech. Grade	No		No[2]
163.62-9(e)	Water Dispersal	No				
163.62-10(b)	Terrestrial Field Dissipation	Yes	Representative Form. Types**	Partial[5]	Ford, 1970, 00001970 Ford, 1971, 00001953	Yes: 24 months[6]
163.62-11(d)	Fish Accumulation	Yes[3]	Tech. Grade	No		Yes: 24 months
163.62-12	Reentry	Yes[4]	Representative Form. Types	Partial	Knaak, 1978, 05003635 Winterlin, 1978, 05001343	Yes: 24 months

* Radio labeled analytical grade or non-radio labeled technical grade.
** 15% Emulsifiable Concentrate and 50% Wettable Powder.

1 For terrestrial noncrop uses, orchard crop uses, field or vegetable crop uses, and forestry uses, the mobility of the test substance and its degradates in soil shall be assessed either by soil thin layer chromatography, soil column, or batch equilibrium (adsorption/desorption).
2- Requested data on leaching will fulfill this requirement.
3- Flow through only.
4- Need data on apples, pecans, and citrus.
5- Protocols used in testing not acceptable.
6- Tree fruit and nut crop use only.

Data Requirements Current as of
June, 1981. Refer to Guidance
Package for Updated Requirements.

TABLE-A (con)

GENERIC DATA REQUIREMENTS AND DATA GAPS
FOR MANUFACTURING-USE DIALIFOR

Guideline Citation	Name of Test Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	Dialifor & Oxon*	Dialifor: No[1] Oxon: No	Jackson, 1966, 00002044[1] Shownig, 1966, 00002043[1]	Yes: 6 months
163.81-2	Acute Dermal Toxicity	Yes	Dialifor & Oxon*	Dialifor: No[1] Oxon: No	Shownig, 1966, 00002043[1]	Yes: 6 months
163.81-7	Acute Delayed Neurotoxicity	Yes	Tech. Grade**	No		Yes: 12 months
163.82-1	Subchronic Oral Toxicity	Yes	Tech. Grade	No		Yes: 12 months
163.82-2	Subchronic (21-day) Dermal Toxicity	Yes	Tech. Grade	Partial[2]	Mastri, 1969,00001946[2]	Yes: 24 months
163.83-1	Chronic Feeding	Yes	Tech. Grade	No		Yes: 48 months
163.83-2	Oncogenicity	Yes	Tech. Grade	No		Yes: 48 months
163.83-3	Teratogenicity	Yes	Tech. Grade	No[1]	Kennedy, 1966, 00002054[1] Kennedy, 1966, 00002055[1]	Yes: 24 months
163.83-4	Reproduction	Yes	Tech. Grade	No		Yes: 48 months
163.84-1-4	Mutagenicity	Yes	Tech. Grade	No		Yes: 24 months
163.85-1	Metabolism	Yes	Tech. Grade	Partial	Bourke, 1970, 00001972 Ford & Friant, 1971, 00001957	Yes: 24 months

* Technical Dialifor and the oxygen analog of Dialifor.

** Technical Grade Dialifor.

[1] Studies have not yet completed validation through Laboratory Audit Program, and are considered invalid for purposes of this Standard. Consult with EPA Laboratory Audit Program prior to initiating studies.

2- Study determined to be supplemental under Laboratory Audit Program, additional testing is required.

Data Requirements Current as of
June, 1981. Refer to Guidance
Package for Updated Requirements.

TABLE-A (con)

GENERIC DATA REQUIREMENTS AND DATA GAPS
FOR MANUFACTURING-USE DIALIFOR

Name of Test Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
RESIDUE CHEMISTRY					
Metabolism in Plants	Yes	Rep. Form.*	Yes	Bourke, 1970, 00001972 Ford, 1971, 00001958 Ford, 1971, 00002[illegible]27 Hercules, 1968, 00002032 Hercules, 1972?, 00002125 Ford, 1971, 00001956	No
Metabolism in Animals	Yes	Rep. Form.	Yes	Bourke, 1970, 00001972 Ford, 1969, 00002024 Ford, 1968?, 00002022 St. John, nd, 05001830	No
Analytical Methods	Yes	Rep. Form.	Yes	Ford, 19?? 00002005 Hercules, 1968, 00002037 Eastman, 1968?, 00002027	No

* from application of representative formulations (45% E.C. and 50% W.P.).

TABLE-A (con)

GENERIC DATA REQUIREMENTS AND DATA GAPS
FOR MANUFACTURING-USE DIALIFOR

Name of Test Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
RESIDUE CHEMISTRY (con)					
Residue Data: RAC					
Pecans	Yes	Rep. Form.*	Yes	Ford, 1969, 00001990 Ford, 1972, 00002130 Ford, 1969, 00001990	No
Citrus Fruits	Yes	Rep. Form.	Yes	Hercules, 1968?, 00002032 Hercules, 1969?, 00001967 Hercules, 1968?, 00001968 Hercules, 1969?, 00001969 Reinking, 1973?, 00002138 Westlake, 1971, 05001345	No
Grapes	Yes	Rep. Form.	Yes	Ford, 1970, 00001984 Ford, 1972, 00002127 Herculos, 1969?, 00001994	No
Raisins	Yes	Rep. Form.	Yes	Ford, 1970, 00001934 Ford, 1973, 00002127	No
Apples	Yes	Rep. Form.	Yes	Herculos, 1969?, 00002034 Ford, 1972, 00001961 Ford, 1972, 00001993	No
Storage Data	Yes	Rep. Form.	Yes	Hercules, 1968? 00002032	No
Residue Data:					
Processed Foods					
Citrus Pulp, Molasses, Citrus Oil	Yes	Rep. Form.	Partial[1]	Westlake, 1971, 05001345 Hercules, 1969?, 00002033 Hercules, 1971?, 00001956	Yes: 24 months
Raisins	Yes	Rep. Form.	Yes	Ford, 1970, 00001984 Hercules, 1973, 00002117	No
Raisin Waste	Yes	Rep. Form.	Yes	Hercules, 1973, 00002117	No
Grape Juice & Pomace	Yes	Rep. Form.	Yes	Ford, 1972, 00002127 Ford, 1970, 00001934	No

TABLE-A (con)

GENERIC DATA REQUIREMENTS AND DATA GAPS FOR MANUFACTURING-USE DIALIFOR

Name of Test Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
RESIDUE CHEMISTRY (con)					
Residue Data:					
Apple Juice & Pomace	Yes	Rep. Form.	Yes	Ford, 1972, 00001993	No
Residues in Meat, Milk, Poultry, and Eggs	Yes	Rep. Form.	Yes	Hercules, 1972?, 00002125 St. John, nd, 00002268 St. John, nd, 05001830 Ford, 1968?, 00002022 Ford, 1969?, 00002024 Taylor, 1969, 00002038 Ford, 1972, 00002129	No

1- Need petition proposing a food additive tolerance of 110 ppm in citrus oil.

Data Requirements are Current
as of June, 1981. Refer to
Guidance Package for Updated
Requirements.

TABLE-A (con)

GENERIC DATA REQUIREMENTS AND DATA GAPS FOR MANUFACTURING-USE DIALIFOR

Guideline Citation	Name of Test Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
ECOLOGICAL EFFECTS						
163.71-1	Avian Single Dose Oral LD50	Yes	Tech. Grade*	No		Yes: 6 months
163.71-2	Avian Dietary LC50	Yes	Tech. Grade	Partial: Waterfowl	Beavers, 1977, 00002139	Yes: 6 months
163.71-4	Avian Reproduction	Yes	Tech. Grade	No		Yes: 18 months
163.72-1	Fish Acute LC50	Yes	Tech. Grade	No		Yes: 6 months
163.72-2	Acute Toxicity to Aquatic Invertebrates	Yes	Tech. Grade	No		Yes: 6 months
163.72-3	Acute Toxicity to Estuarine & Marine Organisms	Yes: Citrus Use	Tech. Grade	Partial: Shrimp	Sleight, 1972, 00002191	Yes: 6 months
163.72-4	Embryolarvae & Life-Cycle	No[1]				
163.122-1	Seed Germination	Yes	Tech. Grade	No		Yes: 24 months
163.122-1	Vegetative Vigor	Yes	Tech. Grade	Yes	Ishitani, 1975, 05006342	No
163.122-2	Growth of Aquatic Plants	Yes	Tech. Grade	No		Yes: 24 months

* Testing required on Technical Grade Dialifor.

1 - Testing may be required pending receipt and results of mobility and persistence studies.

Data Requirements Current as of
June, 1981. Refer to Guidance
Package for Updated
Requirements.

TABLE-B

PRODUCT-SPECIFIC DATA REQUIREMENTS AND DATA GAPS FOR MANUFACTURING-USE DIALIFOR PRODUCTS

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
PRODUCT CHEMISTRY						
163.61-3	Prod. Identity and Disclosure of Ingredients	Yes	Each MUP**	Yes		No
163.61-4	Description of Manufacturing Process	Yes	Each MUP	No		Yes: 6 months
163.61-5	Disc. of Formation of Unint. Ingredients	Yes	Each MUP	Partial[1]	Morrison, 1978, 00004153	Yes: 6 months
163.61-6	Declaration of Ingredient Limits	Yes	Each MUP	Yes		No
163.61-7	Product Analyt. Methods and Data	Yes	Each MUP	Partial: Need data	Hercules, 1957, 00002008 Hercules, 1972?, 00002194 Hercules, 1972, 00002279	Yes: 6 months
163.61-8(7)	Physical State	Yes	MUP***	Yes	Hercules, 1970?, 00001982 Hercules, 1970?, 00001942	No
163.61-8(8)	Density or Specific Gravity	Yes	MUP	No		Yes: 6 months
163.61-8(10)	Vapor Pressure	Yes		No		Yes: 6 monnths
163.61-8(11)	pH	Yes	MUP	No		Yes: 6 months
163.61-8(12)	Storage Stab.	Yes	MUP			Yes: 6 months
163.61-8(13)	Flammability	Yes	MUP	Yes	Hercules, 1970?, 00001982 Hercules, 1970?, 00001942	No
163.61-8(14)	Oxidizing or Reducing Action	Yes	MUP	No		Yes: 6 months
163,61-8(15)	Explosiveness	Yes	MUP	No		Yes: 6 months
163.61-8(16)	Miscibility	Yes	MUP			Yes: 6 months
163.61-8(17)	Viscosity	Yes	MUP	No		Yes: 6 months
163.61-8(18)	Corrosion Characteristics	Yes	MUP	No		Yes: 6 months

* For Currently Registered Product.

** Required for each Manufacturing-use Product.

*** Required for Manufacturing-use Products which are not the same as the Technical Grade of the Active Ingredient. These data are required for Manufacturing-use Dialifor.

Data Requirements are Current as of June, 1981. Refer to Guidance Package for Updated Requirements.

TABLE-B (con)

PRODUCT-SPECIFIC DATA REQUIREMENTS AND DATA GAPS
FOR MANUFACTURING-USE DIALIFOR PRODUCTS

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	MUP**	No[1]	Jackson, 1966, 00002044[1] Schoenig, 1966, 00002043[1]	Yes: 6 months
163.81-2	Acute Dermal Toxicity	Yes	MUP**	No[1]	Schoenig, 1966, 00002043[1]	Yes: 6 months
163.81-3	Acute Inhal. Toxicity	Yes	MUP***	No		Yes: 6 months
163.81-4	Prim. Eye Irritation****	Yes	MUP***	No		Yes: 6 months
163.81-5	Primary Dermal Irritation	Yes	MUP***	No		Yes: 6 months
163.81-6	Dermal Sensitization	Yes	MUP***	No		Yes: 6 months

* For Currently Registered Product.

** Required for Manufacturing-use Products which are not the same as the Technical Grade of the Active Ingredient.

*** Each Manufacturing-use Product or Substantially Similar Product.

**** A demonstration of pH between 1 and 3, or 12 and 14 or a demonstration of dermal irritability will be sufficient to categorize a product as an ocular irritant, and additional testing will not be required.

1- Data not yet completed validation through Laboratory Audit Program, considered invalid for purposes of this Standard. Consult with EPA Laboratory Audit Program prior to initiating testing.

TABLE-C

PRODUCT-SPECIFIC DATA REQUIREMENTS AND DATA GAPS FOR EMULSIFIABLE CONCENTRATE DIALIFOR PRODUCTS

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
PRODUCT CHEMISTRY						
163.61-6	Declaration of Ingredient Limits	Yes	Each E.C. Product**	No		Yes: 6 months
163.61-7	Product Analyt. Methods and Data	Yes	Each E.C. Product	No		Yes: 6 months
163.61-8(1)	Color	Yes	Each E.C. Product	No		Yes: 6 months
163.61-8(2)	Odor	Yes	Each E.C. Product	No		Yes: 6 months
163.61-8(7)	Physical State	Yes	Each E.C. Product	Yes		
163.61-8(8)	Density or Specific Gravity	Yes	EC***	No		Yes: 6 months
163.61-8(9)	Boiling Point	Yes	EC	No		Yes: 6 months
163.61-8(10)	Vapor Pressure	Yes	EC	No		Yes: 6 months
163.61-8(11)	pH	Yes	EC	No		Yes: 6 months
163.61-8(12)	Storage Stab.	Yes	EC	No		Yes: 6 months
163.61-8(13)	Flammability	Yes	EC	No		Yes: 6 months
163.61-8(14)	Oxidizing or Reducing Action	Yes	EC	No		Yes: 6 months
163.61-8(15)	Explosiveness	Yes	EC	No		Yes: 6 months
163.61-8(16)	Miscibility	Yes	EC	No		Yes: 6 months
163.61-8(17)	Viscosity	Yes	EC	No		Yes: 6 months
163.61-8(18)	Corrosion Characteristics	Yes	EC	No		Yes: 6 months

* For Currently Registered Products

** Each Emulsifiable Concentrate Product

*** Each Emulsifiable Concentrate Products or Substantially Similar Product

Data Requirements are Current
as of June, 1981. Refer to
Guidance Package for Updated
Requirements.

TABLE-C (con)

PRODUCT-SPECIFIC DATA REQUIREMENTS AND DATA GAPS FOR EMULSIFIABLE CONCENTRATE DIALIFOR PRODUCTS

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	EC**	No		Yes: 6 months
163.81-2	Acute Dermal Toxicity	Yes	EC**	Yes	Mastri, 1969, 00002269	No
163.81-3	Acute Inhal. Toxicity	Yes	EC**	No		Yes: 6 months
163.81-4	Prim. Eye Irritation	Yes	EC**	No		Yes: 6 months
163.81-5	Primary Dermal Irritation	Yes	EC**	No		Yes: 6 months
163.81-6	Dermal Sensitization	Yes	EC**	No		Yes: 6 months

* For Currently Registered Products

** Each Emulsifiable Concentrate Products or Substantially Similar Product.

Data Requirements are Current as of
June, 1981. Refer to Guidance
Package for Updated Requirements.

TABLE-D

PRODUCT-SPECIFIC DATA REQUIREMENTS AND DATA GAPS FOR WETTABLE POWDER DIALIFOR PRODUCTS

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
PRODUCT CHEMISTRY						
163.61-6	Declaration of Ingredient Limits	Yes	Each W.P. Product**	No		Yes: 6 months
163.61-7	Product Analyt. Methods and Data	Yes	Each W.P. Product	No		Yes: 6 months
163.61-8(1)	Color	Yes	Each W.P. Product	No		Yes: 6 months
163.61-8(2)	Odor	Yes	Each W.P. Product	No		Yes: 6 months
163.61-8(7)	Physical State	Yes	Each W.P. Product	Yes		
163.61-8(8)	Density or Specific Gravity	Yes	WP***	No		Yes: 6 months
163.61-8(10)	Vapor Pressure	Yes	WP	No		Yes: 6 months
163.61-8(11)	pH	Yes	WP	No		Yes: 6 months
163.61-8(12)	Storage Stab.	Yes	WP	No		Yes: 6 months
163.61-8(13)	Flammability	Yes	WP	No		Yes: 6 months
163.61-8(14)	Oxidizing or Reducing Action	Yes	WP	No		Yes: 6 months
163.61-8(15)	Explosiveness	Yes	WP	No		Yes: 6 months
163.61-8(16)	Miscibility	Yes	WP	No		Yes: 6 months
163.61-8(17)	Viscosity	Yes	WP	No		Yes: 6 months
163.61-8(18)	Corrosion Characteristics	Yes	WP	No		Yes: 6 months

* For Currently Registered Product.

** Each Wettable Powder Product.

*** Each Wettable Powder Product or Substantially Similar Product.

Data Requirements are Current
as of June, 1981. Refer to
Guidance Package for Updated
Requirements.

TABLE-D (con)

PRODUCT-SPECIFIC DATA REQUIREMENTS AND DATA GAPS
FOR WETTABLE POWDER DIALIFOR PRODUCTS

Guideline Citation	Name of Test	Are Data Required?	Test Substance	Does EPA Have Data to Partially or Totally Satisfy Requirement?*	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission.
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	WP**	No		Yes: 6 months
163.81-2	Acute Dermal Toxicity	Yes	WP**	Yes	Mastri, 1969, 00003280	No
163.81-3	Acute Inhal. Toxicity	Yes	WP**	No		Yes: 6 months[1]
163.81-4	Prim. Eye Irritation	Yes	WP**	No		Yes: 6 months
163.81-5	Primary Dermal Irritation	Yes	WP**	No		Yes: 6 months
163.81-6	Dermal Sensitization	Yes	WP**	No		Yes: 6 months

* For Currently Registered Product.

** Each Wettable Powder Product or Substantially Similar Product.

[1] Testing of the Manufacturing-use Product is sufficient to satisfy the data requirement.

CHAPTER IV

PRODUCT CHEMISTRY OF DIALIFOR

Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than .1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, or upper limits only for some unintentional ingredients. Subpart D of the Proposed Guidelines (43 FR 29696, July 10, 1978) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency guidelines also require data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g. melting point, boiling point, ambient vapor pressure, and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g. flammability, corrosiveness, or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

Product Chemistry: Manufacturing-use Dialifor

Product Chemistry Profile

Dialifor is the common name for O,O-Diethyl S-(2-chloro-1-pthalimideoethyl) phosphorodithioate). In early phases of development, dialifor was referred to as Hercules 14503. Manufacturing-use and end-use products are marketed under the trade name Torak.

Manufacturing-use dialifor contains a minimum of 90% O,O-Diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate. Dialifor (pure chemical) is a white, crystalline solid with a melting point of 67-69°C, and vapor pressure of less than .001 mm Hg at 35°C. Dialifor is practically insoluble in water, ethyl alcohol, and hexane, but soluble in several organic solvents. Manufacturing-use dialifor is a brown liquid.

Pure or isolated dialifor is not an item of commerce. Commercial, or manufacturing-use dialifor is sold in the form of 90% pure dialifor mixed with some xylene-range aromatic solvents.

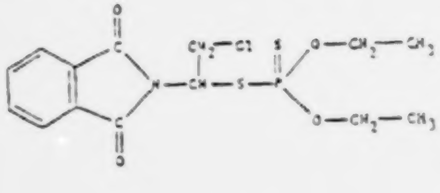
A detailed manufacturing procedure has not been submitted to the Agency. This is essential because the presence of manufacturing impurities is dependent upon the nature of the manufacturing process. The sole registrant, Hercules, Inc., did, however, report some impurities which could be present in technical grade dialifor. Methods for the determination of dialifor in both manufacturing-use and end-use products have been submitted. These methods are lacking in analytical data necessary for the Agency to make a determination on their adequacy.

Product Chemistry Topical Discussions

Chemical Identity

The Agency requires identifying information including chemical names, product names, and numerical codes of all substances known or assumed to be present in pesticide products.

"Dialifor" is the common name accepted by the American National Standards Institute (ANSI) for the chemical 0,0-diethyl S-(2 chloro-1-pthalimidoethyl) phosphorodithioate. The chemical formula is $C_{14}H_{17}O_4NS_2PCL$, and the molecular weight is 393.5. The structural formula is:



Dialifor

Manufacturing-use dialifor is also known by the trade name "Torak" and the company number Hercules 14503. Other synonyms used include: dialifos (ISO) and ENT 27320. Hercules, Inc. is the sole domestic manufacturer of manufacturing-use dialifor. The Chemical Abstracts Registry (CAS) number for dialifor is 10311-84-9. The EPA Shaughnessy number is 102501. The common name, dialifor, will be used throughout this standard in lieu of other chemical or trade names. The nomenclature of dialifor has been adequately defined for the purpose of this Standard.

Manufacturing Processes

A detailed description of the manufacturing process is required because the chemical reactions employed in the manufacturing process and/or the purification of the active ingredient may suggest the presence or absence of potential harmful impurities.

Because this type of information is considered to be confidential business information, a discussion of the specific procedures, equipment and manufacturing conditions required for commercial production of dialifor cannot be published in this Standard. The manufacturing process as submitted by Hercules, Inc., and the identification of impurities, are detailed separately in confidential appendix B.

The procedure submitted by Hercules, Inc. is not sufficiently detailed to satisfy Agency requirements.

Sittig (1977) cites U.S. Patent 3,355,353 by J. D. Jameson (November 23, 1967); assigned to Hercules, Inc. The manufacture of dialifor includes the following procedures:

(a) chloridizing N-vinyl phthalimide to N-(1,2-dichloroethyl) phthalimide,
(b) reacting N-(1,2-dichloroethyl) pthalimide with ammonium diethyl dithiophosphate in acetonitrile, at 25°C initially, then at 50°C,
(c) and cooling and filtering the product, redissolving it in benzene, then washing it with water, until neutral and free of water-soluble materials.

Formation of Unintentional Ingredients

Hercules, Inc. has submitted a confidential statement of ingredients for manufacturing-use dialifor. This too is confidential business information and cannot be discussed here. It is however, discussed in confidential appendix B. The statement provided by Hercules, Inc. is missing required information on a portion of the manufacturing-use product. These data are required.

Manufacturing-use dialifor has been analyzed for the presence of N-nitrosamines (Morrison, 1978, 00004153). The sensitivity of the test was .3 ppm. A Varian chromatograph was used, with a thermal energy analyzer, and the recovery values were in the range of 62%. No polar nitrosamines were detected.

Active Ingredient Limits in Pesticide Products

Manufacturing-use dialifor is comprised of 90% minimum of the active ingredient O,O-Diethyl S-(2-chloro-1-phthalimidoethyl) phosphorodithioate. Hercules, Inc. has certified the lower limit of the active ingredient as a 90% racemic (d and l) mixture of the isomers of dialifor. Depending on the manufacturing process conditions, up to 10% of technical impurities can be expected.

Product Analytical Methods and Data

Ultraviolet analytical methods for the identification and quanitification of dialifor in the manufacturing-use product and end-use products have been submitted (Hercules, Inc., 1967, 00002008 and 1972?, 00002194). In both cases, a suitable amount of sample is dissolved in methylene chloride and then isolated from interfering materials on a silicic acid chromatographic column. The absorbance is then measured in an ultraviolet spectrophotometer at 300 um. The peak is then compared with an internal standard.

The second method (Hercules, Inc., 1972, 00002194) describes fractionation in two different solvents and the subsequent measurement of the ultraviolet absorption of each fraction. In xylene, any unreacted N-(1,2-dichloroethyl) pthalimide (N-DCEP), dialifor and an unidentified column "residue" (which includes the oxygen analog of dialifor) are separated and measured in the appropriate fractions.

Two other methods regarded as technically satisfactory for the determination of dialifor and its impurities have been described (Hercules, 1972, 00002279). One is a liquid chromatographic method that uses an ultraviolet photometric detector, and the other method employs gas chromatography. The latter is used exclusively for the determination of impurities. In both cases, internal standards are used and the peak areas for dialifor and the internal standard (corrected for a response factor obtained by calibration with a known mixture) are used to calculate the percentage of dialifor.

Although the referenced methods for the identification and quantification of dialifor in products are regarded as satisfactory, required analytical data (recoveries, background, sensitivity, etc.) are lacking. Therefore, the Agency is unable to determine whether or not these methods are fully acceptable.

Physical and Chemical Properties

For every pesticide product, the Agency requires data on certain physical and chemical properties useful for identification purposes or for evaluation of hazard potential. These data are required on the technical grade of the active ingredient, and on the manufacturing-use product, if different. Certain data are required on pure or isolated dialifor, as well as on the manufacturing-use product.

The physical and chemical properties of technical grade dialifor have been reported (Hercules, 1970?, 00001982, 00001942):

Physical State, Color: crystalline white

Solubility (grams for 100 g solution at 20°C)

Water	Less than 1 g
Acetone	76 g
Chloroform	62 g
Ethyl Alcohol	Less than 1 g
Ethyl Ether	50 g
Hexane	Less than 1 g
Isophorone	40 g
Xylene	57 g

The lack of quantitative solubility data (expressed in g/100 ml of the solvent at 20°C or in terms of ppm in distilled water or solvents commonly used for pesticides) in some solvents constitutes the data gap described for the solubility of technical grade dialifor.

Melting Point:	67°-69°C
Vapor Pressure:	0.0001 mm Hg at 35° by Menzie's method
Explosiveness:	may explode if heated at 70°C

Little data are available on the physical/chemical properties of manufacturing-use dialifor:

Physical State:	liquid
Color:	brown
Flammability:	flash point above 200°F

Product Chemistry: End-use Formulations

Product Chemistry Profile

End-use dialifor products are available in emulsifiable concentrate and wettable powder formulations. Emulsifiable concentrates contain 45% dialifor (and related compounds) and wettable powders contain 50% dialifor (and related compounds). The analytical methods described in the manufacturing-use section of this chapter apply to these end-use formulations as well. Data were not available on the physical/chemical properties of any end-use product.

Product Chemistry Topical Discussions: End-Use Products

Chemical Identity

Dialifor end-use products are marketed under the trade names Torak-P®, Torak-G®, and Torak®.

Active Ingredients in Pesticide Products

Three 4 pound per gallon emulsifiable concentrates containing dialifor as the sole active ingredient are currently registered. These products contain 45% dialifor (and related compounds). One 50% wettable powder is also registered.

Product Analytical Methods and Data

See discussion in manufacturing-use section for details.

Physical and Chemical Properties

The only data available is the physical state. Emulsifiable concentrates are liquids and wettable powders are solids.

CHAPTER V

ENVIRONMENTAL FATE OF DIALIFOR

Use Pattern Profile

Dialifor is an insecticide-acaracide registered for control of:

1. apple maggot, plum curculio, and red banded leaf roller on apples,
2. pacific spidermite and grape leafhopper on grapes,
3. citrus rust mite, citrus red mite, texas citrus mite, citrus snow scale, and brown soft scale on citrus, and
4. black pecan aphid, hickory shuckworm, pecan nut case bearer, pecan weevil, spittle bugs, yellow pecan aphid, and serpentine leadminer on pecans.

Dialifor is formulated as a 50% wettable powder, and a 4 lb./gallon emulsifiable concentrate. The wettable powder is registered for use as a foliar spray on apples. The 4 lb./gallon emulsifiable concentrate is registered for use as a foliar spray on grapes, citrus, and pecans.

On apples, applications can be made at 7-14 day intervals for nearly an entire season (1-6 applications per season). Applications are made beginning at petal fall. The dialifor product registered for use on apples was never placed on the market.

On grapes, applications can be made at 1-4 month intervals for up to 2 times per year. Applications are made in early April or May and July or August (when needed). Most appplicators are certified or work under the supervision of certified applicators. Current labels on emulsifible concentrate dialifor products intended for application on grapes restrict use of Dialifor to California.

On citrus, applications can be made at 3 month intervals if fruit is present at first application, for up to 2 times per year. Applications are made post-bloom and in summer. Most applicators are certified or work under the supervision of certified applicators.

On pecans, applications can be made at 7-10 days intervals for up to 12 times per year. Applications are made beginning in February-March in southern states, and continuing through late summer. Applicators are certified or are supervised by certified applicators.

The major site for dialifor use was on citrus during the early 1970's. Pecans began to account for an increasing amount of total poundage throughout the mid and later 1970's.

Most dialifor usage today is on citrus and pecans. However, the only existing dialifor products are those which were manufactured 1-3 years ago and are still being marketed. Available data indicate that dialifor is applied to less than 1 percent of citrus, pecan, grape, and apple acreage in the United States.

Registered application rates are listed below:

FORMULATION	SITE	TYPE OF APPLICATION	APPLICATION RATE
Wettable Powder (50%)	Apples	Foliar	1.5-2.25 lb AI/A
Emulsifiable Concentrate (4 lb/gal)	Grapes	Foliar	1.0 lb AI/A
	Citrus	Foliar	1.25-5.0 lb AI/A
	Pecans	Foliar	1.0-2.0 lb AI/A

Environmental Fate: Dialifor

Environmental Fate Profile

Preliminary data suggest that dialifor does not leach through clay or loamy sand soils. More than 96% of the applied dialifor remained in the upper 1 inch and 99% remained in the upper 2 inches of these soils after they were eluted with 2.5 acre-inches of water. A linear decline of subsurface applied dialifor was reported under greenhouse conditions with a half-life of about 28 days. In this study, the oxygen analog of dialifor was present in unknown amounts throughout a 99-day period. Dialifor was more persistent in a moist Willamette soil maintained in sealed containers in the dark at 20°C. Under these conditions the half-life of dialifor, at 0.1 and 1 ppm, was about 5 months.

The field dissipation of dialifor is biphasic, with an initial rapid rate of decline followed by a slower decline rate. Levels of residues recovered from the top 4 inches of California loam, Mississippi fine sandy loam, and Nebraska and Delaware slit loams ranged from 5.8 to 57% of the applied amount 9 weeks after treatment with emulsifiable concentrates of dialifor at 5 lb ai/A. The amount of dialifor that dissipated after 9 weeks varied from 0% over the following 5.5 months, to 50% over the following 3.5 months.

In a photolysis study, dialifor oxygen-analog, phthalamide, phthalamic and o phthalic acids, N-(8-chlorovinyl) phthalamide, and phosphorothioate derivatives were detected in preparations containing dialifor. The mechanisms of formation of these compounds cannot be determined based on the available information.

Exposure Profile

Dialifor is registered as an insecticide/acaracide for use on agricultural crops. An emulsifiable concentrate containing 45% dialifor (and related compounds) is registered for use on grapes, pecans, and citrus. A wettable powder containing 50% dialifor (and related compounds) is registered for use on apples. Both formulations are applied as sprays for foliar treatment.

All Formulations

The use of airblast machines (which direct the spray upward) increases the potential for exposure via spray drift to humans, livestock or wildlife outside the application site. Although the extent to which airblast machines are used for dialifor application is not known, available data indicate that worker exposure will occur primarily through the dermal route.

Data are insufficient to establish the potential for groundwater contamination, or bioaccumulation.

Emulsifiable Concentrates

In studies using an emulsifiable concentrate, dialifor was applied to oranges at a rate of 3.75 pounds active ingredient per acre with a commercial sprayer. Respirator cartridges and filters were used to measure exposure to gaseous and particulate dialifor, respectively. Air samples were also taken from operator breathing zones. Dermal exposure was measured by analyzing dialifor residues on shirts worn by the operators for timed intervals.

Results showed that respiratory exposure to gaseous and particulate dialifor would be <0.01 and 0.143 mg/8-hour workday, respectively. Analysis of air samples taken from operator breathing zones showed a potential inhalation exposure of approximately 0.05 mg/day during hard work (respiratory rate of 11 liters per minute). Total potential dermal exposure to dialifor under the same conditions ranged from 49 to 66 mg/8-hour workday (mean 58 mg/day).

Wettable Powder

Exposure studies conducted with the wettable powder formulation of dialifor also showed that operator exposure would be predominantly dermal. These studies were conducted under conditions similar to those used in the emulsifiable concentrate studies, except that dialifor was applied to apples at 2.0 lb ai/A. Tests were conducted on two different days at the same location.

Data from the first spraying showed that respiratory exposure to gaseous and particulate dialifor would be <0.01 and 0.03 mg/8 hour workday, respectively. Air samples taken from the breathing zone of the operator showed that approximately .029 mg/day would be available for absorption by inhalation during hard work. Total dermal exposure was approximately 38 mg/8-hour workday. Data from the second spraying supported the initial observation that respiratory exposure to gaseous and particulate dialifor would be < 0.01 and 0.03 mg/8-hour workday. Breathing zone measurements showed approximately 0.01 mg/day available for inhalation. Total dermal exposure resulting from the second spraying was about 15 mg/8-hour workday.

Farmworker Exposure

A number of field studies have been conducted to measure fieldworker exposure to residues of dialifor in grapes, and to measure dislodgeable residue concentrations after application. Many of these studies were initiated following reports of worker illness after reentry into treated areas.

Summary Table

Location	Crop/ Application Rate	Residue Levels		Interval	Dislodgeable Residues
		Skin	Clothing		
Madera, California	Grapes; 1 lb ai/A		Trousers: .42-1.6 ug/cm^2	Unknown	Unknown
Lodi, California	Grapes; 1 lb ai/A	1.24 ug/cm^2		50 days	Unknown
Fresno, California	Grapes; 1 lb ai/A	1.54 ug/cm^2		71 days	Unknown
Madera, California	Grapes; 1 lb ai/A (airblast)			0 days	2.3 ug/cm^2
Madera, California	Grapes; 1 lb ai/A			60 days	dialifor: 107 ng/cm^2 oxon: 21.6 ng/cm^2
				60 days	dialifor: 60.3 ng/cm^2 oxon: 22.7 ng/cm^2
	Grapes; 2@ 1 lb ai/A*			60 days	dialifor: 99.6 ng/cm^2 oxon: 26.2 ng/cm^2
Soledad, California	Grapes; 1 lb ai/A (boom sprayer)			0 days	2.1 ug/cm^2
Lodi, California	Grapes; 1 lb ai/A (speed sprayer)			0 days	.41 ug/cm^2

Fowler, California	Grapes; 1 lb ai/A	42 days	.09 ug/cm^2
San Joaquin, California	Grapes; 1 lb ai/A	at harvest	.13 ug/cm^2

* one application 2 months and one three months before harvest

Half-lives ranged from 9-15 days. The Agency is unable to determine what foliar dislodgeable residue levels are safe for reentry because of extensive gaps in the toxicology data base. However, the Agency has decided to accept the 75-day reentry interval established by the State of California for the use of dialifor on grapes. This reentry interval corresponds to what California believes is a safe foliar dislodgeable residue level of 0.06 ug/cm^2.

Topical Discussions: Manufacturing-use Dialifor

Physico-Chemical Transformation
Metabolism
Mobility
Field Dissipation
Accumulation
Reentry

Physico-Chemical Transformation 163.62-7

Hydrolysis

Hydrolysis data are required to support the registration of all manufacturing-use chemicals regardless of the intended end uses of products formulated from the manufacturing-use product.

Four studies were reviewed; however, no valid data on the hydrolysis of dialifor were available.

All studies specified in Section 163.62-7(b) are needed to assess the hydrolysis properties of manufacturing-use dialifor.

Photolysis

A photodegradation study in water is required to support the registration of each formulated end-use product intended for terrestrial (except greenhouse and domestic outdoor), aquatic, and forestry use and for any aquatic impact use which results in direct discharges into the aquatic environment. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Photodegradation studies on soil surfaces are required to support the registration of each formulated end-use product intended for crop uses and forestry uses. Such studies are also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Two related studies were reviewed and considered invalid because the studies did not indicate if dark controls were employed. In addition, the purity of the starting materials were not specified. However, one of these studies (Ford, 1971, 00001956) contains valid data on dialifor degradation products. The identified compounds are: dialifor oxygen-analog, phthalamid, o-phthalic acid, phthalamic acid, N(B-chlorovinyl)phthalamide, and phosphorothioate derivatives.

Due to the deficiencies in protocol followed in these studies, the mechanism(s)of formation of these compounds cannot be determined. All data specified in Section 163.62-7(c) are needed to determine the effect of light on dialifor.

Metabolism 163.62-8

Data on metabolism are required to determine the nature and availability of pesticide residues to rotational crops and to help in the assessment of potential disposal and reentry hazards.

Soil

Aerobic soil metabolism studies are required to support the registration of all products intended for terrestrial end-uses or terrestrial/aquatic (forest) end-uses.

Two soil metabolism studies were reviewed and provide preliminary data on the degradation of dialifor in soil. An acetone solution of dialifor was applied to topsoil in pots under greenhouse conditions in a manner designed to minimize volatilization and photodegradation (Hercules, Inc., 1968, 00002003). The half-life of dialifor was approximately 28 days; 8% was recovered after 99 days. The oxygen analog of dialifor was present throughout this period in quantities that cannot be verified. In a related study (Freed et al., 1979, 05008242), the half-life of dialifor, at applications of .1 and 1 ppm, was determined to be about 5 months in moist Willamette soil maintained in sealed containers. However, this study did not indicate whether aerobic or anaerobic conditions prevailed. This decreases the value of the study for determining the aerobic metabolism of dialifor in soil.

All data specified in Section 163.62-8(b) are needed to determine the aerobic metabolism of dialifor in soil. Anaerobic soil metabolism data are not required because dialifor is not used for field and vegetable crops.

Mobility 163.62-9

Data on mobility are required to determine pesticide residue movement in the environment.

Leaching

Data are required to support the registration of products intended for the following end-uses: domestic outdoor use, greenhouse use, terrestrial noncrop use, orchard crop use, field or vegetable crop use, forestry use, aquatic use, and aquatic impact use involving direct discharge only.

For terrestrial noncrop uses, orchard crop uses, field or vegetable crop uses, and forestry uses, the mobility of the test substance and its degradates in soil shall be assessed either by soil thin layer chromatography, soil column, or batch equilibrium (adsorption/desorption). For domestic outdoor uses, greenhouse uses, aquatic uses, and aquatic impact uses, the mobility of the test substance and its degradates in soil shall be assessed only by batch equilibrium (adsorption/desorption).

The leaching potential of dialifor (6 lb/gal emulsifiable concentrate) was studied in three soils (characteristics given in Table 1) in 6-inch aluminum leaching columns eluted with 2.5 inches of water (Ford, 1971, 00001953). Gas chromatographic analysis of dialifor residues showed that 96% of the applied dialifor remained in the upper 1 inch and more than 99% remained in the upper 2 inches of soil. Dialifor does not appear to leach through clay or loamy sand soils. For registration purposes, these results must be regarded as preliminary, studies in soil leaching require the use of 30-cm columns leached with 20-acre-inches of water on four soil types.

All studies specified in Section 163.62-9(b) are needed to determine the leaching potential of dialifor and its degradation products.

Table 1. Characteristics of Soils Used for Leaching Studies

Soil Origin	Sand (%)	Silt (%)	Clay (%)	Organic Matter (%)
Nebraska[a]	20	30	46	3.60
Florida	82	16	2	0.68
Delaware	28	28	44	1.60

[a] The percentage of sand, silt, and clay added up to only 96%, not 100%. However, the texture classification is considered appropriate. Adapted from Ford, 1971, 00001953.

Volatility

Laboratory volatility studies using nonradioisotopic analytical techniques are required to support the registration of all products intended for greenhouse use and to evaluate reentry hazards from cholinesterase-inhibiting pesticides.

No data on the volatility of dialifor are available.

Dialifor is a cholinesterase inhibiting pesticide and the possibility of a reentry hazard exists with current uses of dialifor. Consequently, all data specified in Section 163.63-9(c) are needed to determine the volatility of dialifor.

Adsorption/Desorption

A laboratory study using radiosiotopic or nonradioisotopic analytical techniques is required to support the registration of all products intended for terrestrial end-uses, terrestrial/aquatic (forest) end-uses, aquatic end-uses,and aquatic impact end-uses (if the pesticides are discharged directly into the aquatic environment).

No data were available. Data necessary to meet this requirement will be met by data requested on leaching.

Water Dispersal

Data on the water dispersal of dialifor are not required because dialifor is not registered for an aquatic use.

Field Dissipation 163.62-10

Field dissipation studies under actual use conditions are required to support the registrations of all products intended for terrestrial (except greenhouse) end-uses, aquatic end-uses, and terrestrial/aquatic (forest) end-uses.

Terrestrial

Terrestrial field dissipation studies using representative formulated products are required to support the registration of each product intended for terrestrial (except greenhouse) end-uses.

Three field dissipation studies were reviewed and two were considered valid. Dialifor residues were determined in the top 4 inches of field plots treated with emulsifiable concentrates (EC's) of dialifor (Ford, 1970, 00001970). Residue levels 9 weeks after treatment of Delaware silt loam with a 6 lb/gal EC, at 1 to 5 lb ai/A, were 0.57 and 2.1 ppm, respectively. Residue levels remained unchanged 5 months later in the soil treated at 1 lb ai/A. Residue levels 9 weeks after treatment of Nebraska silt loam with 4 and 6 lb/gal EC at 5 lb ai/A were 1.6 and 1.9 ppm, respectively. Residue levels dissipated an additional 50% 5 months later in the soil treated with 4 lb/gal EC. Residue levels in Mississippi fine sandy loam and California loam were 0.43 and 0.47 ppm 9 weeks after treatment with 4 lb/gal EC at 5 lb ai/A.

Similar field dissipation data were collected 1 year later using the same soils described above after treatment at a rate of 5 lb ai/A with an unspecified type of emulsifiable concentrate (Ford, 1971, 00001953). Residue levels 9 weeks after treatment were 0.04, 0.78, 0.24, and 0.55 ppm in the California, Mississippi, Nebraska, and Delaware soils, respectively. Residue levels in the latter two soils 5.5 months post treatment were 0.12 and 0.15 ppm, respectively.

In both of the above studies, preapplication and immediate postapplication data were not obtained; therefore, reliable half-life estimates cannot be derived from the data. The data indicated that dialifor dissipation is a biphasic phenomenon with an initial rapid rate of decline followed by a slower decline rate.

These data alone are insufficient to assess the rate or the impact of the dissipation of dialifor in the field. Additional data are needed in the following use area.

- Tree fruit and nut crop - Section 163.62-10(b)(2)

Data are needed to determine the dissipation rate of the following formulations of dialifor:

45% ai emulsifiable concentrate
50% ai wettable powder

Accumulation 163.62-11

Fish

A laboratory study employing radioisotopic or nonradioisotopic analytical techniques is required to support the registration of all products intended for terrestrial noncrop, tree fruit/nut crop, and field/vegetable crop end-uses;

aquatic food crop and noncrop end-uses; terrestrial/aquatic (forest) end-uses; and aquatic impact (indirect discharge) end-uses.

No data on the accumulation of dialifor in fish are available. Registrants have the option of supplying the required fish accumulation study or of establishing that dialifor will not reach water and will not persist in water (ie. a nominal half-life of 4 days or less), and that dialifor possesses an octanol/water partition coefficient of less than 1,000.

Data specified in Section 163.62-11(d) for flow through study only are needed to determine if dialifor will accumulate in fish.

Reentry 163.62-12

Reentry intervals are required to support the registration of all products for which the Agency has determined that a reentry hazard exists for persons reentering treated sites. Dialifor is an acetyl-cholinesterase inhibiting pesticide which presents a hazard to persons reentering treated fields.

According to Knaak et al. (1978, 05003635), the half-life of dialifor residues on grape leaves varies with the dilution rate; e.g., initial dislodgeable residues at 2 ug/cm^2 had half-lives of 9 and 13 days when sprayed (1 pound active ingredient per acre) in 100 and 25 gallons of water, respectively. Workers became ill when they entered treated vineyards 39 days after application; highly significant ($P<0.001$) lower blood cholinesterase levels were found in workers 1 and 6 days after the reported illness. California's Department of Food and Agriculture (unpublished communication) indicates that an interval of 65 days is generally required to reach a safe dislodgeable foliar residue level of less than 0.06 ug/cm^2 when the initial dislodgeable residue level is as high as 2.3 ug/cm^2. Because field data are highly variable, onsite residue tests, performed prior to reentry may be necessary.

In another study of the same fields where the above worker illness occurred (Winterlin et al. 1978, 05001343), dislodgeable residues of dialifor and its oxygen analog were 0.06-0.107 ug/cm^2 (5.6-9.9 ppm) and 0.022-0.027 ug/cm^2 (1.7-2.6 ppm), respectively, 59 days after application at 1 pound active ingredient per acre.

For each crop, the registrant is required to propose an acceptable reentry interval. This proposed interval may be based on any of the following:

a. the longest (most restrictive) existing interval;
b. data on dissipation of foliar residues (decline curve), on human exposure to those residues; and on the inherent toxicity of dialifor;
c. a determination of the time after which no detectable foliar residues occur under appropriate climactic conditions, in the geographical area in which dialifor will be applied.

The Agency is adopting the 75 day reentry interval established by the State of California for the use of dialifor on Grapes (California Administrative Code, January 4, 1979, Article 23, 2479 (H), Field Worker Safety). Registrants have the option of accepting the 75 day reentry interval or of supplying exposure data, a dislodgeable residue decline curve and establishing an appropriate reentry interval based on this data

Reentry data must be submitted for the use of dialifor on citrus, pecans, and apples.

CHAPTER VI

TOXICOLOGY OF DIALIFOR

Introduction

The first section of this chapter discusses the toxicity of dialifor as an active ingredient. The data discussed here pertain to the properties or effects of dialifor as an active ingredient, and are relevant to an evaluation of the risks and benefits of all products containing dialifor. This type of data is referred to as "generic" data. "Generic" data gaps in the Toxicology data base are discussed in this section. Product-specific Toxicology data gaps (in acute toxicity testing) for currently registered manufacturing-use dialifor products are also identified here.

The second section of this chapter discusses the toxicity of products currently formulated from manufacturing-use dialifor. These products are grouped by type of formulation and the toxicity of each type of formulation is discussed separately. The toxicity of emulsifiable concentrate dialifor products is discussed first, followed by a discussion of the toxicity of wettable powder dialifor products.

"Generic" data on the toxicity of dialifor, as an active ingredient, normally supplies sufficient information to establish the subchronic and chronic toxicities of formulated products. However, acute toxicity data on each end-use product, or substantially similar product, is required and must be supplied. If these data are available, they are discussed in the formulation sections. If gaps in the acute toxicity data base exist, they are identified.

A. Manufacturing-use Dialifor

As discussed in Chapter III, the majority of company submitted toxicology studies on dialifor were completed by Industrial Biotest Laboratories (IBT). A number of these studies have been validated through the Laboratory Audit Program and the results of the audit are presented in the topical discussions. Some studies have not yet been validated through the Laboratory Audit Program, and this too is indicated. However, all IBT studies have been screened for indications of possible dialifor related adverse effects. IBT studies which do not indicate adverse effects are considered invalid for purposes of registration (fulfilling Agency testing requirements) until they have completed the validation process in the Laboratory Audit Program. Registrants are encouraged to consult with the EPA Laboratory Audit Program prior to initiating this category of testing.

Manufacturing-use Dialifor Toxicology Profile

Acute Toxicity

Single dose oral toxicity testing of dialifor shows a sex difference in rats that is characteristic of many O,O-Diethyl phosphate derivatives. This sex difference is not as significant in other (non rat) test species. Available data indicate that manufacturing-use dialifor is acutely toxic, with reported oral LD50 values ranging from 5-71 mg/kg body weight in rats. In rabbits, reported oral LD50 values range from 35-79 mg/kg body weight. In mice, reported oral LD50 values range from 39-64 mg/kg body weight, and in dogs the reported oral LD50 value is 97 mg/kg.

This suggests that dialifor is very acutely toxic by the oral route. Symptoms observed (salivation, diarrhea, sedation and tremors) are typical of parasympathomimetic action and are similar to those observed for other members of the organic phosphate family.

All acute oral toxicity testing on technical grade dialifor was conducted by Industrial Biotest Laboratories (IBT) and has not yet completed validation through the Laboratory Audit Program. For purposes of this Standard, these data do not fulfill Agency testing requirements. Therefore, acute oral toxicity testing on technical grade dialifor is a data gap.

In addition, acute oral toxicity testing of the oxygen analog of dialifor is required because the Agency has established that this degradation product may constitute up to 12.5% of weathered residues on food and in the field. Oxygen analogs of organophosphate insecticides are also traditionally more toxic than the parent compounds.

Available data on the dermal toxicity of technical dialifor suggest that the dermal LD50 in rabbits is 145 mg/kg body weight. This suggests that technical grade dialifor is very acutely toxic by the dermal route.

The acute dermal toxicity testing discussed above was conducted by Industrial Biotest Laboratories (IBT) and has not yet completed validation through the Laboratory Audit Program. For purposes of this Standard, these data are considered invalid and a data gap exists for acute dermal toxicity testing of technical grade dialifor.

In addition, acute dermal toxicity testing of the oxygen analog of dialifor is required because the Agency has established that this degradation product may constitute up to 12.5% of weathered residues on food and in the field. Oxygen analogs of organophosphate insecticides are also traditionally more toxic than the parent compounds.

Available data demonstrate that both atropine sulfate and 2-PAM have antidotal action on acute oral dialifor toxicity.

Chronic Toxicity

Because dialifor is structurally similar to the human teratogen Thalidomide, teratogenicity testing of dialifor is of particular concern. Three studies, conducted by Industrial Biotest Laboratories, assessing the possible teratogenic effects resulting from administration of dialifor to rabbits and monkeys were reviewed. These studies have not yet completed validation through the Laboratory Audit Program, and are therefore considered to be invalid for purposes of this Standard. The Agency did screen these studies for indications of adverse effects. The studies do suggest that dialifor may be fetotoxic and teratogenic in rabbits. However, no definitive conclusions can be reached on the teratogenicity of dialifor.

In addition to the three IBT studies on dialifor, the Agency also reviewed a teratogenicity study in hamsters conducted by Jane Robens. This study also indicated that dialifor may be teratogenic. However, the reported results were not considered to be significant due to a high rate of maternal mortality. No definitive conclusions can be drawn on the teratogenic potential of dialifor.

The Agency reviewed several animal metabolism studies which provide insight into the fate of ingested dialifor in animals. The majority of ingested dialifor appears to be excreted in the urine and feces. The results of biochemical analyses indicate that the primary metabolic fate of dialifor involves the conversion to phthalamic acid, which is excreted in the urine rather than dialifor itself.

Clinical Trials

The Agency reviewed one study involving the oral administration of dialifor to male and female humans. At dosages of .03 mg/kg/day, 20-30% inhibition of blood cholinesterase and aliesterase activities occurred. No effects were noted at dosages of .01 mg/kg/day. This study was conducted by Industrial Biotest Laboratories and has been determined to be supplemental through the Laboratory Audit Program.

Accident Reports

The Agency has reviewed an accident report documenting a fieldworker poisoning incident in the State of California. In addition, through communication with the State of California, the Agency identified an earlier record of a farmworker poisoning incident in 1973 involving worker exposure to dialifor and phosalone residues. The first poisoning incident (1973 in Fowler California) involved 32 grape pickers who harvested grapes 42 days after application of dialifor. The second poisoning incident (1976 in Madera California) involved 118 grape pickers. Available data indicate that reentry occurred 15 days after application. In both instances, workers were exposed to residues of both dialifor and phosalone (another organophosphate insecticide).

In both incidents, fieldworkers were treated for cholinesterase poisoning and no fatalities were reported.

Topical Discussions: Manufacturing-use Dialifor

Acute Toxicity

Acute Oral Toxicity (163.81-1)

The minimum data required for establishing the acute oral toxicity of manufacturing-use dialifor (LD50) is one test on the technical chemical and on each manufacturing-use product, preferably using the laboratory rat. Because available residue chemistry data indicate that dialifor-oxon may form in the field and may constitute a significant amount of residues in food, the Agency is also requiring acute oral toxicity testing on this degradation product.

Technical grade dialifor, for purposes of acute oral toxicity testing is considered to be equivalent to manufacturing-use dialifor. Requested testing on technical grade dialifor will fulfill requirements for the currently registered manufacturing-use product.

Several studies were available to assess the acute toxicity of technical grade dialifor, and the results of these studies are summarized in the following table:

Species	Sex	Dose Range (mg/kg)	# animals per dose	LD50	Toxicity Category*	MRID# Reference
rabbits	F	16-79	4	35 ± 9	—	Jackson, 1966, 00002044
rats	M	35-118	4	53 ± 6	—	Schoenig, 1966, 00002043
	M	23-79	4	43 ± 6	—	"
	M	35-118	4	71 ± 7	—	"
	F	3-10	4	5 ± 1	—	"
mice	M	23-79	4	39 ± 7	—	"
	F	35-118	4	64 ± 4	—	"
rabbits	M	35-118	4	58 ± 6	—	"
	F	35-118	4	79 ± 7	—	"
dogs	M	53-178	2	97 ± 5	—	"

* These studies are unaudited IBT studies. The Agency is unable to establish Toxicity Categories for this type of data.

Signs of toxicity in rabbits (Jackson, 1966, 00002044) included diarrhea, salivation, sedation, and tremors preceding death (all signs of anti-cholinesterase poisoning). Necropsy of rabbits that died showed inflammation of the mucosal lining of the stomach and small intestine. No changes were found in the animals surviving the 14-day observation period. Similar findings at necropsy were observed in rabbits by Schoenig (1966, 00002043).

Signs of toxicity noted by Schoenig (1966, 00002043) were similar in rats, mice and dogs. These were typical symptoms of anti-cholinesterase poisoning. However, there were no gross pathological findings at necropsy in any of the three species tested.

An additional study on the acute oral toxicity of "recrystallized AC14503" reported LD50 values in male and female rats of 69 mg/kg and 5 mg/kg respectively. Because the test substance was not fully identified, the value of this study is diminished. However, the LD50 values reported in this study are in general agreement with those reported in other studies on the same species utilizing technical grade dialifor.

All of the studies discussed above were conducted by Industrial Biotest Laboratories. These studies have not yet completed validation through the Laboratory Audit Program. Therefore, these studies must be considered invalid for purposes of this Standard.

No testing of the acute oral toxicity of dialifor-oxon was available.

Acute Dermal Toxicity (163.81-2)

The minimum data required for establishing the acute dermal toxicity of manufacturing-use dialifor is one test on technical dialifor and on each manufacturing-use product, preferably using the albino rabbit. Because dialifor-oxon may constitute a significant portion of weathered residues in food and in the field, the Agency is also requiring testing on the oxon.

Technical grade dialifor, for purposes of acute dermal toxicity testing is equivalent to the currently registered manufacturing-use product. Requested testing on technical grade dialifor will fulfill requirements for acute dermal toxicity testing on the currently registered manufacturing-use product.

One study was available to assess the acute dermal toxicity of technical grade dialifor. This study is summarized below:

Species	Sex (#/dose)	Single dermal dose range (mg/kg)	Skin	LD50 (mg/kg)	Toxicity Category*	Reference
rabbit	M (2)	79-267	clipped intact	145 ± 8	—	Schoenig, 1966, 00002043
rabbit	M (2)	79-267	clipped abraded	145 ± 8	—	"

* These studies are unaudited IBT studies. The Agency is unable to establish Toxicity Categories for this type of data.

Signs of toxicity in this study were typical of anti-cholinesterase poisoning, e.g. lethargy, salivation, and tremors.

Local skin reactions in all animals consisted of slight to moderate erythema.

This study was conducted by Industrial Biotest Laboratories and has not yet completed validation through the Laboratory Audit Program. Therefore, this study must be considered invalid for purposes of this Standard.

No testing was available on the oxygen analog.

Acute Inhalation Toxicity (163.81-3)

The minimum testing required to establish the acute inhalation toxicity of manufacturing-use dialifor is one test on technical grade dialifor and on each manufacturing-use product preferably in the laboratory rat. This testing is required if technical dialifor causes a respirable vapor, or if 20% or more of the aerodynamic equivalent is composed of particles not larger than 10 microns.

Technical grade dialifor, for purposes of acute inhalation toxicity testing is equivalent to the currently registered manufacturing-use product. Requested testing on technical grade dialifor will fulfill requirements for acute inhalation toxicity testing on the currently registered manufacturing-use product.

Acute inhalation testing is required and is unavailable on technical grade dialifor. Registrants have the option of supplying the test or of demonstrating that dialifor will not cause a respirable vapor, or that if a respirable vapor is produced, the equivalent aerodynamic diameter of 20% of the particulate is less than 10 microns.

Primary Eye Irritation (163.81-4)

The minimum testing required to establish the irritability of manufacturing-use dialifor to the eye is one test on the manufacturing-use product, preferably using the albino rabbit.

This testing need not be completed if data are submitted which indicate that manufacturing-use dialifor is either a dermal irritant or possesses a pH of 1-3 or 12-14. A test substance that causes dermal irritation or that has a pH of 1-3 or 12-14 will be judged corrosive to the eye..

One study was available to assess the primary eye irritation potential of technical dialifor (Shoenig, 1966, 00002043). Using albino rabbits, both undiluted dialifor (100 mg) and a 5% [w/v] suspension in propylene glycol (0.1 ml) was tested for eye irritation potential. Washing versus not washing the test material after 1 minute of contact was also tested. In all animals, there were no visible effects on the cornea. Irritation of both the iris and conjunctiva was noted within 1 hour, but all effects were reversible within 72 hours to 7 days. The primary deficiencies in this study were the small number of animals used and that both eyes were treated. This study will not satisfy guideline requirements because of flaws in protocol followed in this study.

Primary Dermal Irritation (163.81-5)

The minimum testing needed to establish the irritability of manufacturing-use dialifor to the skin is one test on the manufacturing-use product preferably using the albino rabbit.

This testing need not be conducted if data are submitted which establish that the pH of manufacturing-use dialifor is 1-3 or 12-14. A product with a demonstrated pH of 1-3 or 12-14 will be considered corrosive.

One study was available to assess the primary dermal irritation of manufacturing-use dialifor (Shoenig, 1966, 00002043). The results indicate that dialifor was only mildly irritating to the skin of rabbits. However, because of errors in protocol and reporting, this study cannot be considered valid.

Dermal Sensitization (163.81-6)

The minimum testing required to assess dermal sensitization for the manufacturing-use product is an intradermal test on the manufacturing-use product preferably using the guinea pig.

No testing is available, and testing is required.

Acute Delayed Neurotoxicity (163.81-7)

The minimum testing required for acute delayed neurotoxicity is one test on technical dialifor. This testing is required because dialifor is known to cause esterase depression.

One study was available to assess the acute delayed neurotoxicity of technical dialifor (Jackson, 1968, 00001998). However, this study was conducted by Industrial Biotest Laboratories and has been invalidated by the Laboratory Audit Program.

Testing is required.

Subchronic Effects

Subchronic Oral Toxicity (163.81-1)

The minimum testing needed is one test on technical grade dialifor in two mammalian species, preferably the rat and dog.

There are six subchronic oral toxicity tests on technical grade dialifor. Three of these studies were conducted in dogs and three were conducted in rats. The following table summarizes these studies:

Species	Sex (#/dose)	Dose Level Tested	Duration	Classification/ Deficiencies	Results	Reference MRID
dog	M-F (1)	0, 20, 100 500 ppm	14 days	Supplementary** 1) too few animals used 2) no control groups 3) too few variations monitered 4) observation period too short for dog sub-chronic study	1) RBC + Plasma ChE inhibited at all dose levels (lowest = 20 ppm) 2) Decreased food intake (all doses) 3) Decreased body-weight at high dose (500 ppm) 4) No gross pathology observed	*Schoenig, 1966 MRID# 00002048
rats	M-F (3)	0, 10, 20, 50, 100, 200, 500, 1000 ppm	14 days	Supplementary** 1) too few animals used/dose 2) too few variables moritered 3) observation period too short for rat sub-chronic study	1) dose related decrease in RBC, plasma + brain ChE at all doses (lowest dose tested = 10 ppm) 2) 100 ppm and above produced gross signs of anti-ChE poisoning and mortality (33%, 50%, 67%, 100%) 3) depressed weight gain at higher doses	*Wolf, 1966 MRID# 00002047
rats	M-F (10)	0, 20, 50 ppm	90 days	Invalid by IBT Audit	———	*Wolf, 1966 MRID# 00002049

Species	Sex (#/dose)	Dose Level Tested	Duration	Classification/ Deficiencies	Results	Reference MRID
dogs	M-F (2)	0, 1, 3, 10, 30, 100 ppm	98 days	Supplementary** 1) too few animals used/dose 2) 98 days is too short for a dog subchronic oral study	1) ChE depression; NOEL for RBC and plasma 1 ppm, for brain 300 ppm 2) At 100 ppm, muscular weakness, hypersensitivity 3) All other parameters normal (blood, urine, gross + necroscopy)	*Baran, 1966 MRID# 00002051
rats	M-F (21)	0, 0.3, 1, 3, 10, 30 ppm	90 days (28 day recovery)	Supplementary (determined by IBT Audit) 1) IBT Audit Final 2) Too few animals used for ChE measuremetns (only 6/measurement) 3) ChE only measured. Other variables not monitered.	1) ChE depression; NOEL for RBC and plasma = 3 ppm; brain = 10 ppm 2) plasma ChE depression fully recovered in 28 days 3) RBC and brain ChE only partial recovery in 4 weeks 4) Results confirmed by repeat study using 6M-F and measuring ChE activity after 3 and 13 weeks.	*Wolf, 1966 MRID# 00002050
dogs	M-F (-)	0, 50, 100 ppm	2 years	Invalid by Audit	———	*Baran, 1968 MRID#00002028

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*All studies conducted by IBT. Validations have been completed on MRID#00002050 (supplementary), MRID#00002028 (Invalid); and MRID#00002049 (Invalid).

**Pending Final IBT Audit

The three dog studies were conducted by Industrial Biotest Laboratories. Of these three studies, only one (Baran, 1968, 00002028) has completed validation through the Laboratory Audit Program. This study has been determined to be invalid.

The other two studies utilizing dogs as the test species were screened for indications of dialifor-related adverse effects. Schoenig (1966, 00002048) showed cholinesterase (ChE) inhibition in red blood cells (RBC) and plasma at all doses tested (down to 20 ppm in the diet). No gross pathology was observed. However, this study was of only 14 days duration, too short for a subchronic study in dogs. Furthermore, too few animals were tested, there were no control groups, and too few variables were monitored. This study was inadequate as a subchronic oral test, although ChE depression was noted down to 20 ppm. In another study, Baran (1966, 00002051) also fed technical dialifor to dogs and noted ChE depression in red blood cells (NOEL 1 ppm), plasma (NOEL 1 ppm) and brain (NOEL 30 ppm). All other parameters were normal (blood counts and chemistry, urinalysis, gross pathology and microscopy).

These studies are flawed and do not satisfy Agency testing requirements.

All rat subchronic studies were conducted by Industrial Biotest Laboratories. Wolf (1965, 00002047) fed rats technical grade dialifor for 14 days and observed dose related decreases in RBC, plasma and brain ChE at all doses (down to 10 ppm). Gross signs of anti-ChE poisoning and mortality (increasing with dose) were noted at 100 ppm and above. This study is flawed and does not fulfill Agency requirements.

In a subsequent study, Wolf (1966, 00002049) fed rats technical dialifor for 90 days. This study has completed validation through the Laboratory Audit Program and has been determined to be invalid.

In a separate 90 day ChE study (Wolf, 1966, 00002050) rats were fed technical dialifor and NOEL's were established for ChE inhibition as follows: RBC= 3 ppm, plasma= 3ppm, brain= 10 ppm. Plasma ChE recovered in 28 days and there was partial recovery of RBC and brain ChE in the same time frame. This study has completed validation through the Laboratory Audit Program and has been determined to be supplemental. It will not fulfill Agency requirements for subchronic testing in the rat.

Although data do indicate that dialifor is a cholinesterase inhibiting pesticide, the Agency is unable to set a No Observed Effect Level (NOEL) at this time. Additional testing is required.

Subchronic 21-Day Dermal Toxicity (163.82-2)

The minimum data required for subchronic 21-day dermal toxicity is one test utilizing technical grade dialifor, preferably in the albino rabbit.

There were no data available on technical grade dialifor. However, testing was completed utilizing the emulsifiable concentrate product (Mastri, 1969, 00001946). The clipped, intact backs of rabbits (3/sex/dose) were exposed to 0, 1, 5 and 25 mg/kg of emulsifiable concentrate dialifor (4 lbs./gal) for a total of 22 applications (30 days) at 6 hours/application. Test results are summarized in the following table:

Dose (mg/kg)	Mortality	ChE Levels (Percent of Controls) Plasma	RBC	Brain
0	0/6	100%	100%	100%
1	0/6	102%	90%	76%
5	1F/6*	71%	35%	50%
25	1M, 2F/6*	31%	25%	21%

* Gross signs of anti-cholinesterase poisoning were salivation and diarrhea.

The data in the table show that brain ChE was depressed to varying degrees at all dose levels (NOEL not determined); both RBC and plasma ChE NOEL's were 1 mg/kg. Gross signs of anti-cholinesterase poisoning and mortality were observed at higher doses. Slight irritation and erythema were noted at the application site.

The "negative" results reported on the other parameters which were measured, i.e. hematology, urinalysis, necropsy and histopathology, were questioned in the Laboratory Audit Report. These negative findings cannot be regarded as valid, and this study must be considered only supplementary.

Additional testing is required.

Subchronic Neurotoxicity (163.82-5)

The minimum data required for subchronic neurotoxicity testing is one test on the technical grade chemical, using either the adult hen or a mammalian species. This testing may be required if the results of the requested acute delayed neurotoxicity test is positive.

Subchronic 90-Day Dermal Toxicity (163.82-3)

Testing is not required because the use of dialifor does not involve purposeful application to skin or result in significant human dermal exposure.

Subchronic Inhalation Toxicity (163.82-4)

Testing is required if the results of the requested acute inhalation toxicity test indicate that repeated exposure at a concentration that is likely to be toxic occurs under normal conditions of use.

Chronic Effects

Chronic Feeding (163.83-1)

The minimum data required for an assessment of the chronic toxicity of dialifor is one test on the technical grade chemical, preferably using the laboratory rat.

One two-year chronic feeding study in rats was available (Wolf, 1968, 00002021). However, this study was conducted by Industrial Biotest Laboratories and has been determined to be invalid through the Laboratory Audit Program.

Additional testing is required.

Oncogenicity (163.83-2)

The minimum data required to assess the potential oncogenic effects of dialifor is testing on the technical grade chemical in two mammalim species, preferably the rat and mouse.

No data were available. Testing is required.

Reproductive Effects

Teratogenicity (163.83-3)

The minimum data required to assess the potential teratogenic effects of dialifor is testing in two mammalian species using the technical chemical.

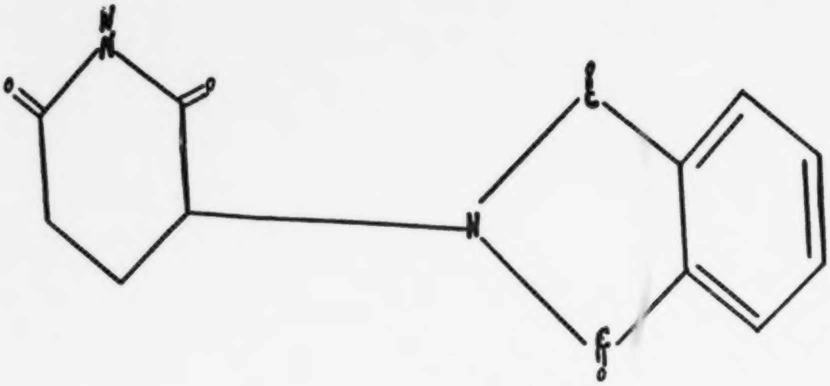
Dialifor is structurally related to the known human teratogen Thalidomide (see Figure 1), therefore testing of dialifor is of special concern.

There are four studies which were available to assess the teratogenic potential of dialifor. Three of these studies were conducted by Industrial Biotest Laboratories and have not yet completed validation through the Laboratory Audit Program. These studies therefore, do not fulfill teratogenic testing requirements for dialifor.

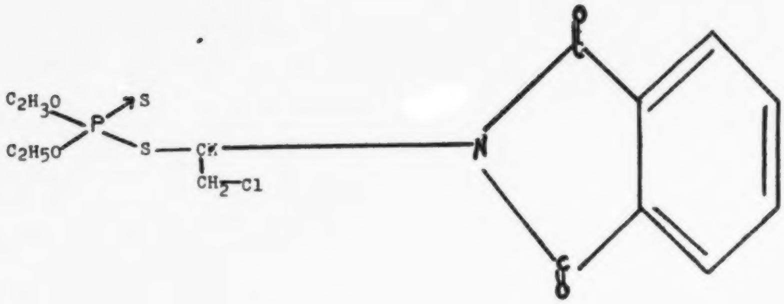
A screen of these studies for indications of adverse effects provided some useful information.

In one study (Kennedy, 1966, 00002054), groups (N=10) of rabbits were given 1, 3, 10 and 25 mg/kg dialifor, 75 mg/kg Thalidomide (positive control) or 260 mg/kg corn oil on days 6 through 18 (inclusive) of gestation. High maternal mortality was noted in the 10 mg/kg (70%) and 25 mg/kg (100%) dialifor treated groups. No "abnormal" young (based on a limited number of parameters) were noted in controls or at 1 or 10 mg/kg dialifor. Thirty "abnormal" young were observed in the Thalidomide positive controls. The abnormality described was severe clubbing of the extremeties. In addition, in the 3 mg/kg dialifor treatment group three of the young showed umbilical hernias (examination for skeletal development did show normally formed skeletal structures) and one was partial acranius. At doses of 1, 3 and 10 mg/kg dialifor, a decrease in fetal viability was seen, and at 10 mg/kg, an increase in fetal resorption occurred. These results suggest possible dialifor related teratogenic and adverse reproductive effects. However, no definitive conclusions can be made regarding the teratogenicity of dialifor.

In a similar study, also conducted by Industrial Biotest Laboratories, Jackson and Kennedy (1966, 00002055) repeated the experiment described above using 1 and 3 mg/kg dosages of dialifor. In the Thalidomide treated positive control group (75 mg/kg), twenty four "abnormal" young (severe clubbing of the extremeties and talipes varus) were reported. No abnormalities were reported



THALIDOMIDE


C_2H_3O
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C_2H_5O
S
CH
CH_2–Cl
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DIALIFOR

Figure 1

in the untreated controls or the test groups receiving dialifor. There was no evidence of maternal mortality in any group, although the number of resorption sites was greater in the test groups receiving dialifor than in the untreated controls. This suggests a possible dialifor related reproductive effect. There was also a slight decrease in the number of viable young in the dialifor treated groups, suggesting possible fetotoxic effects. However, no definitive conclusions can be made regarding the teratogenicity and fetotoxicity of dialifor.

In a third study, also conducted by Industrial Biotest Laboratories, female stumptailed macques were used to test the teratogenic potential of dialifor (Vondruska, 1969, 00001976). The design and execution of this study was severly flawed (e.g. no controls, limited anatomical observations, etc.). The monkeys were given dialifor (1 mg/kg; N=10) or Thalidomide (5 or 10 mg/kg; N=3 and 6) during gestation (days 23-21; 24-30; 23-30). Monkeys given dialifor showed an average depression of 35% in RBC and plasma ChE activity, but no gross effects were noted in any of the seven major organs or major bones examined. All of the fetuses in the Thalidomide treated groups displayed anomalies of the appendages, but no gross changes were observed in major organs examined.

The final study reviewed by the Agency on the teratogenic potential of dialifor was conducted by Jane Robens (1970, 05001994). The test species used was hamsters. Dosages in the dialifor treated groups ranged from 0 to 500 mg/kg, and dosages in the Thalidomide positive control groups ranged from 300-1200 mg/kg. The results suggest possible dialifor related reproductive effects. However, this study cannot be considered a valid test for the teratogenic potential of dialifor because maternal mortality was significant at all dialifor dose levels, the Thalidomide positive controls did not produce dose related teratogenic effects, and only gross external signs of teratology were monitored.

Additional testing is required. One of the species tested must be either rabbits or monkeys. The species chosen for teratogenicity testing of dialifor is of special concern because the teratogenic effects of Thalidomide are more reliably reproduced in rabbits and monkeys. Because dialifor is structurally similar to Thalidomide, there is a good possibility that the mode of action may be similar, and that testing in rabbits (more economically feasible than testing in monkeys) would provide better information.

Reproduction (163.83-4)

The minimum data required to assess the reproductive effects of dialifor is testing in one mammalian species, preferably the laboratory rat, using technical grade dialifor and lasting for two generations.

A three generation rat reproduction study, conducted by Industrial Biotest Laboratories, was reviewed by the Laboratory Audit Program and has been determined to be invalid (Arnold, 1968, 00002029).

Testing is required.

Mutagenicity

The following studies represent only the minimum requirements for data on the potential heritable effects of technical dialifor.

1. A mammalian *in vitro* point mutation test.
2. A sensitive submammalian point mutation test (bacteria, fungi, insect).
3. A primary DNA damage test (i.e., sister chromatid exchange or unscheduled DNA synthesis).
4. A mammalian *in vitro* cytogenetic test. If this test suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other Toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

These requirements should be considered as an interim guide and not final Agency policy.

Metabolism

Metabolism (163.85-1)

The minimum data required to assess the metabolic fate of dialifor is a single dose test using the analytically pure grade of the active ingredient in a radioactively labeled form.

Although some data were available which provide insight into the metabolic fate of dialifor, none of the studies are adequate to fulfill Agency requirements.

In one study (Bourke, *et al*., 1970, 00001972), rats were given a single oral dose (1 mg/kg) of ^{14}C labeled dialifor. Within 50 hours most of the radioactivity (80%) was recovered in the urine and feces. Of the remaining 20% in the animal, 7-13% was associated with the digestive tract, with only .2%-.1% remaining in the liver and kidney. In another part of this study, five male and five female rats were given 1 mg/kg of labeled dialifor. Excreta were collected for 7 days. The results were similar to those reported in the 50-hour study, with 50% of the radioactivity present in the urine, and 40% in the feces within 48 hours. The radioactivity in the urine was "tentatively" identified as phthalamic acid (by R_f and infrared spectral analysis).

In another report, also utilizing rats, Ford and Friant (1971, 00001957) attempted to identify dialifor metabolites in urine. Each of 16 rats were given 4 mg of radiolabeled dialifor in corn oil via stomach tube. Urine was collected for 24 hours and was subject to numerous biochemical procedures to identify the compounds containing the radioactive label. The results suggest that the primary metabolic fate of dialifor involves conversion to phthalamic acid, which is excreted in the urine rather than dialifor itself.

The studies described above are not adequate because the purity of the test material was not specified, the specific labeling (^{14}C) of dialifor was not given, no time course of radioactive label recovery or total recovery was reported (only in Ford and Friant, 1971, 00001957), and identification of the metabolites was insufficient.

Additional testing is required.

Clinical Trials

The Agency reviewed a study assessing the effects of dialifor (unspecified formulation) on plasma and RBC ChE activity and plasma aliesterase activity in humans (Greco, 1970, 00001950). Oral administration of dialifor to male and female human subjects caused 20-30% inhibition of blood cholinesterase and aliesterase activities at doses of .03 mg/kg/day for four weeks to .10 mg/kg/day for ten days. At these doses, partial to complete recovery occurred within seven weeks. No effects were noted (NOEL) at .01 mg/kg/day for two weeks. No changes were observed in any of the hematological variables measured at any of the dose regimens tested.

This study was conducted by Industrial Biotest Laboratories and has been determined to be supplemental.

Antidotes

The Agency reviewed one study (Mastri, 1968, 00002020) which assessed the efficacy of atropine sulfate and 2-PAM as antidotes in rats. This study is summarized below:

Treatment Schedule	Oral LD50 (mg/kg)
a. Technical Grade Dialifor alone (35-119 mg/kg)	71 ± 7.3
b. Technical Grade Dialifor (52-400 mg/kg) + 30 minutes Atropine Sulfate (17.5 mg/kg)	approx. 140
c. Technical Grade Dialifor (118-400 mg/kg) + 30 minutes 2-PAM Cl (50 mg/kg)	266 ± 31.3
d. Technical Grade Dialifor (79-267 mg/kg) + 30 minutes Atropine Sulfate (17.5 mg/kg) 2-PAM Cl (50 mg/kg)	177 ± 21

Toxic signs noted were typical of anti-ChE poisoning. No gross pathologic findings were noted in any of the animals at necropsy.

This study is adequate to establish an acute oral LD50 for technical grade dialifor in male rats of 71 ± 7 mg/kg. It is also adequate to demonstrate that both atropine sulfate and 2-PAM have antidotal action (increases the LD50) on the acute oral toxicity of dialifor. 2-PAM was more effective as an antidote than atropine sulfate.

This study was conducted by Industrial Biotest Laboratories and has not yet completed validation through the Laboratory Audit Program. The LD50 value reported in this study cannot be considered valid.

B. Emulsifiable Concentrate Dialifor

Emulsifiable Concentrate Dialifor Toxicology Profile

As discussed in Chapter III, the majority of toxicity testing on dialifor was conducted by Industrial Biotest Laboratories. A number of these studies have completed validation through the Laboratory Audit Program, and this is indicated in the topical discussions where applicable. Several studies have not yet completed this validation step, and this too is indicated. For purposes of this Standard, these studies do not fulfill Agency requirements for testing.

Acute Toxicity

Data discussed in the manufacturing-use dialifor portion of this chapter suggest that technical grade dialifor is extremely toxic via the oral route. No acute oral toxicity data are available on any end-use emulsifiable concentrate product. The Agency assumes that existing emulsifiable concentrate dialifor products are also extremely toxic via the oral route. The acute dermal toxicity of emulsifiable concentrate dialifor places these products in category II.

Topical Discussions: Emulsifiable Concentrate Dialifor

Acute Toxicity

Acute Oral Toxicity (163.81-1)

No data were available to assess the acute oral toxicity of any currently registered emulsifiable concentrate product. The Agency will assume, based on acute testing of technical grade dialifor, that existing emulsifiable concentrate dialifor products are extremely toxic. Testing is required.

Acute Dermal Toxicity (163.81-22)

One study was available to assess the acute dermal toxicity of emulsifiable concentrate formulations containing dialifor. The LD50 in male rabbits is 326 ± 18 mg/kg when applied to intact skin (Mastri, 1969, 00002269). Signs of toxicity were typical of anti-cholinesterase poisoning, e.g., ataxia, salivation, tremors, fibrillations, diarrhea and lethargy. Pale red erythema and edema were noted at the application site in all groups. Necropsy revealed no other gross pathologic alterations.

This study has been certified by the Laboratory Audit Program and is of sufficient quality to fulfill testing requirements. The dermal LD50 value places EC formulations in category II, corresponding to a moderate acute dermal toxicity potential. No additional testing is required

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Acute Inhalation Toxicity (163.81-3)

An acute inhalation toxicity test is required on each EC formulation unless evidence is submitted indicating that the particular product will not produce a respirable vapor or that if a respirable vapor is produced, the equivalent aerodynamic diameter of 20% of the particulate is less than 10 microns.

One study (Hathaway, 1969, 00001974) was reviewed and was found to be inadequate because of numerous serious flaws in protocol and study conduct.

Additional testing is required.

Primary Eye Irritation (163.81-4)

No data were available to assess the eye irritation potential of any EC product. Testing is required.

Primary Dermal Irritation (163.81-5)

No data were available to assess dermal irritability of any EC product. Testing is required.

Dermal Sensitization (163.81-6)

No intradermal tests for dermal sensitization in laboratory animals are available on any EC formulation. Testing is required.

C. Wettable Powder Dialifor

As described in Chapter III, the majority of toxicity testing of dialifor was conducted by Industrial Biotest Laboratories. A number of these studies have completed validation through the Laboratory Audit Program, and this is indicated in the topical discussions where applicable. Several studies have not yet completed validation, and this too is indicated. For purposes of this Standard, these studies do not fulfill Agency requirements for testing.

Wettable Powder Dialifor Toxicology Profile

Acute Toxicity

Data discussed in the manufacturing-use portion of this chapter suggest that technical grade dialifor is extremely toxic via the oral route. No data were available to assess the acute oral toxicity of the wettable powder product. The Agency will assume that it too is extremely toxic via the oral route. Acute dermal toxicity testing has been provided and the results place wettable powder dialifor in category II.

Topical Discussions: Wettable Powder Dialifor

Acute Toxicity

Acute Oral Toxicity (163.81-1)

No data were available to assess the acute oral toxicity of wettable powder dialifor. Testing is required.

Acute Dermal Toxicity (163.81-2)

One study was available to assess the acute dermal toxicity of wettable powder dialifor. The LD50 determined in this study for male rabbits (Mastri, 1969, 00003280) is 735 ± 213 mg/kg on intact skin. Signs of toxicity were typical of anti-cholinesterase poisoning and skin reactions were mild. Necropsy revealed no other pathologic alterations.

This study has been certified by the Laboratory Audit Program and is considered to be adequate for Agency testing requirements. The reported LD50 value places wettable powder dialifor in toxicity category II, corresponding to a moderate acute dermal toxicity. No additional testing is required.

Acute Inhalation Toxicity (163.81-3)

An acute inhalation study is required on the wettable powder product unless evidence is submitted showing that either the wettable powder product will not produce a respirable vapor, or that if a respirable vapor is produced, the equivalent aerodynamic diameter of at least 20% of the particulate is less than 10 microns.

One study was reviewed and found to be inadequate (Hathaway, 1969, 00001975) because of numerous serious flaws in protocol and study conduct.

Testing on the manufacturing-use product will fulfill requirements for this wettable powder product.

Primary Eye Irritation (163.81-4)

No data were available on the wettable powder product. Testing is required.

Primary Dermal Irritation (163.81-5)

No data were available on the wettable powder product. Testing is required.

Dermal Sensitization (163.81-6)

No intradermal testing is available for the wettable powder product. Testing is required.

CHAPTER VII

RESIDUE CHEMISTRY

A. Introduction

For any pesticide which has uses that may directly result in residues on food or feed, the Agency sets an allowable residue level, or tolerance, for each commodity on which it may occur. A tolerance level for a particular chemical on a particular commodity is a function of the chemical's toxicity, the percentage of an average daily diet comprised by the commodity, and the amount of residue that can be expected to occur on that commodity at the maximum directed rate of application. The total amount of chemical to which a person may be exposed from all sources should always be less than the toxicological estimate of a safe "Allowable Daily Intake."

The insecticide dialifor is used in the control of a variety of spiders, mites, and scales in the following food crops: citrus fruits, apples, grapes, and pecans. The majority of its current use is in pecans. Tolerance levels of 3.0 ppm (citrus), 1.5 ppm (apples), 1 ppm (grapes), and .01 ppm (pecans) have been established (CFR 180.326). In addition, tolerance levels of 0.15 ppm (red meat), .006 ppm (milk and dairy products), .05 ppm (poultry), and .01 ppm (eggs) have also been established.

B. Manufacturing use Dialifor

1. Residue Chemistry Profile

Dialifor is an insecticide-acaricide used to protect citrus fruits, apples grapes and pecans.

Dialifor is not considered to be systemic in plants, although its residues will penetrate into the peel or rind of fruit. The residues consist primarily of dialifor and of lesser amounts of the oxygen analog. Available data indicate that up to 12.5% of remaining residues consist of the oxygen analog.

The oxygen analog is thought to form through photodegradation. The amounts of the oxygen analog which are present in different crops indicate that hydrolysis, not oxidation, is the favored route of metabolic degradation. The two initial fragments which result from hydrolysis are N-1-hydroxy-2-chloroethyl phthalimide and O,O-Diethyl thiophosphoric acid. The phthaloyl moiety is extensively metabolized to phthalamic and o-phthalic acids which are found it plants in the form of salts. The thiophosphoric moiety is metabolized to thiophosphoric and phosphoric acids which are reabsorbed and enter into the cellular pool.

The metabolism in animals appears to be similar to that which occurs in plants. However, whereas plants retain their metabolic products, animals eliminate the majority of them in the urine. In addition, animals are unable to completely degrade the parent compound, which is found intact in the feces.

Adequate dialifor-specific and dialifor-oxon-specific analytical methods are available for detection of residues on citrus fruits, apples, grapes, and their derived by-products: meat, milk, poultry and eggs. Data are available on residues in these commodities.

Available residue data show that the combined residues of dialifor and dialifor-oxon found in and on the above commodities, resulting from presently registered uses, do not exceed the established tolerances in 40 CFR 180.326. The use of currently recommended application rates and preharvest intervals will insure residue levels below tolerance limits on the raw agricultural commodities at harvest. There are no records of regulatory incidents involving the enforcement of these tolerances.

2. Required Labeling

Labels of dialifor wettable powder and emulsifiable concentrate products must contain the following restrictions:

Grapes, Apples, citrus, and Pecans: "Do not combine emulsifiable concentrate formulations with Bordeaux mixtures. Do not feed or allow livestock to graze on cover crops grown in treated areas. Do not contaminate food or feedstuffs (storage and disposal). Do not apply when weather conditions favor drift from treated areas."

Topical Discussions

a. Uptake, Distribution, and Metabolism in Plants

In addition to what may remain of an original application of the chemical, residues may also consist of the chemical's metabolites, as formed by the plant crop to which it was applied. The major and minor pathways of the chemical's absorption, transformation, and distribution can be deduced experimentally from the analysis of radiolabeled applications. Applications by various routes, for example to the roots or leaves, will show differences in absorption rates. The distribution of the chemical and its metabolites can be examined by measuring the radioactivity present in various plant fractions. Isolated metabolites can then be characterized by chromatography, partitioning, or electrophoresis. Metabolic transformations often result in an increase of polarity of the foreign chemical to facilitate elimination. Metabolites characterized as highly polar may have undergone conjugation with naturally occurring amino acids, sugars, or sugar acids. Further chemical analysis can help identify the exact nature of the conjugations. Other possible major transformations can occur by hydrolysis, oxidation/reductions, or the breaking of unstable bonds. The absorption, distribution, and metabolic fate of the chemical determine the potential quantity and identity of pesticide residues in plants used for food or feed.

Dialifor is a foliar insecticide and acaricide, and its use is primarily directed to leaves. The absorption, distribution, and metabolic fate of dialifor was investigated by J.B. Bourke et al (1970, 00001972). When ^{14}C-ring labeled dialifor is applied to a surface of bean or tomato leaf or injected into the plant stem, the bulk of radioactivity remains at the site of application. Autoradiograms show that the slight movement that has occurred after 18 days of application is primarily through the leaf veins, thus indicating that such movement was in the form of water insoluble metabolites moving in the xylem. Direct injection into tomato fruit did not show any movement of the pesticide through the parent plant, thus proving that dialifor does not kill insects or mites by systemic action.

Additional studies on isotopic dilution techniques were conducted on citrus plants by J.J. Ford et al .(1971, 00001958, 1972, 00002127, and Hercules, 1968, 00002032), in support of the preceding radioautography data. Four miniature orange trees (Calamondin), in full leaf and fruit were sprayed to runoff with ^{14}C-ring labeled dialifor in methylene chloride and the recovered runoff was assayed. Samples of leaves and fruits were Soxhlet-extracted with acetone for internal residues, and all the residues were identified by thin layer chromatography.

Residues of dialifor were also determined by GLC. Distribution of radioactivity in samples taken at 1-, 4-, 8-, 12-, and 14-week intervals indicated the presence of dialifor per se ,its oxygen analog, and two metabolites, the phthalamic acid and the o-phthalic acid.

Immediately after application, 83% of the total ^{14}C-labeled residue was identified as dialifor. The following changes were observed:

Dialifor	65% of the total labeled material after 1 week. 51% of the toal labeled material after 14 weeks.
Dialifor-oxon	17% of the total labeled material after 1 week. 9% of the total labeled material after 14 weeks.
Phthalamic and o-phthalic acids	18% of the total labeled material after 1 week. 39% of the total labeled material after 14 weeks.

The level of radioactivity on the leaves was found to be 15-20 times larger than that on the fruits. No radioactivity was detected in the fruit pulp or in the new growth after 12 weeks. Whatever internal residues were found did not decrease appreciably after 14 weeks; therefore, they did not undergo complete degradation.

Dialifor shows little tendency to translocate from foliar deposits or to be absorbed into fruit pulp. Residues are found primarily in the peel or rind, and they tend to be extremely persistent, as shown by decline curves.

In vitro hydrolysis and photogegradation studies (Ford, 1971, 00001956) show that the decomposition products are phthalamic and o-phthalic acids.

The major pathway of metabolic degradation of dialifor in plants begins with the formation by hydrolysis of N-1-hydroxy-2-chloroethyl phthalimide and O,O-diethyldithiophosphororic acid. The former is metabolized to phthalamic acid and o-phthalic acids, found in the plant in the form of salts. The minor pathway involves the formation by oxidation of the oxygen analog, which is generally detected in amounts up uo 12.5% of the total residue (Hercules, 1972?, 00002125). The fate of the thiophosphate fragment has been thoroughly studies by R.J. O'Brien, who found that thiophosphoric and phosphoric acids are reabsorbed and become part of the cellular pool.

The residues in apples, apple pomace, oranges, orange pulp, orange oil, grapes, grape pomace, and raisins which are open to toxicological considerations are dialifor per se and its oxygen analog (Eastmen, 1968?, 00002027). No oxygen analog as component of the total residue has been reported for pecans.

b. Metabolism in Animals

From one feeding study with rats (Burke et al., 1970, 00001972), using radio-labeled material, it was indicated that the metabolism of dilaifor in animals apparently proceeds in a manner similar to that in plants, with its conversion to dialkyldithiophosphoric acids and to compounds containing the phthalic acid moiety. Small amounts of dialifor per se are transferred to the tissues.

^{14}C radiotracer studies involving the ingestion of dialifor by large ruminants (cows, goats) have not been submitted. Feeding studies using unlabeled dialifor show that animals are unable to completely degrade the parent pesticide. Thus, beef calves maintained from 2 to 8 weeks on a dry diet containing an excessive level of 60 ppm of dialifor (J.J. Ford, 1969, 00002024) showed up to 0.4 ppm of dialifor per se in fat tissues and up to 0.30 ppm in liver tissues.

In another study, dairy cows maintained for three weeks on a diet containing 40 ppm dialifor showed 0.0001 ppm to 0.013 ppm of dialifor per se in milk (Ford, 1968? 00002022). Based on these data, maximum residues in milk should be slightly above 0.01 ppm or 0.26 ppm on a fat basis.

In a final study by St. John et al .(1971, 05001830), dialifor was fed to a dairy cow at a level of 5 ppm for 4 days. Neither dialifor nor its oxygen analog were found in milk. Dialifor was absent in the urine, and about 3% of the total dialifor fed was found in the feces. The metabolism of dialifor in animals appears to be similar to that in plants. Overall, the fate of dialifor in animals is adequately described.

c. Analytical Methods

Metabolism data indicate that dialifor per se and up to 12.5% of its oxygen analog comprise the bulk of the residue found in plants and animals.

The regulatory method for the analysis of dialifor in crops is contained in Vol. II of the Pesticide Analytical Manual, as Method I, and was submitted by Hercules (J.J. Ford, 19??, 000020005). In this method, 200 g of ground apple or orange peel or juiced orange pulp samples are extracted 3 times with 400 ml. each of acetone in a Waring blender at high speed for 5 minutes. The extracts are filtered through a coarse fritted funnel, combined and concentrated to a volume of 900 ml. of acetone. Following a multistep cleanup procedure, the dialifor residues can be detected by gas liquid chromatography employing a phosphorus-specific potassium chloride thermionic detector. The sequence of this clean-up is as follows:

1- Methylene chloride water partition
2- 5 Component absorbent material
3- Celite partition column
4- Acetonitrile-hexane partition
5- Alumina column

Appropriate clean-up procedures are selected depending on the commodity undergoing analysis. For instance, for apples, steps 1,2, and 3 are only applied; for oranges, steps 1, 4, and 5 are applied. When operated as described (Ford, 1968, 00002005) the thermionic detector responds to dialifor at the one nanogram level. The sensitivity of the method is 0.01 ppm. This method is also so specific that none of the other common organophosphorus pesticides interfere (the retention time of dialifor is considerably greater than that of any of these materials).

The method was validated by the Food and Drug Administration laboratory in Los Angeles, California, and by EPA (1971). The average recovery obtained by EPA for dialifor in orange samples fortified at 1.5 to 3 ppm was 92.2%, and individual values varied from 84% to 98%. Recoveries were slightly higher at the same levels before final clean-up steps were preformed.

This method has only been validated for dialifor per se but is said to be capable of detecting the oxygen analog with good sensitivity.

A thin layer chromatography-cholinesterase inhibition method has been described as suitable for detecting residues of dialifor and its oxygen analog in foods (Hercules, 1968, 00002037). Briefly, the technique utilizes enzymatic inhibition as the detection system in conjunction with 5-bromoindoxyl acetate as the chromogenic agent.

The procedure is capable of detecting 2-3 ng of dialifor and it oxygen analog. The method was validated (Eastmen, 1968, 00002027). Recovery studies of the oxygen analog on apples fortified at levels of 0.02-0.08 ppm ranged from 82% to 100%. Recoveries of the oxygen analog on oranges fortified at levels of 0.04-0.20 ppm ranged from 85-100%.

Acceptable methods for the determination of dialifor in beef tissues and milk were submitted by Hercules and are published in the Pesticide Analytical Manual, Vol. II, as Method II and Method III.

Method II consists of extracting the residue from meat, fat and meat by-products with an acetone-chloroform mixture. An aliquot is evaporated to dryness and the residue dissolved in hexane-acetonitrile. After partitioning and evaporation, the residue is cleaned up on an alumina column. The residue is determined using the gas chromatographic parameters specified in Method I. This method was subject to a method trial in EPA laboratories with beef suet. Levels of fortification were at 0.12 ppm and 0.06 ppm of dialifor with recoveries ranging from 96% to 104% in the first case, and 80% to 96% in the second case. The sensitivity of the method is 0.005 ppm.

In Method III, the milk fat is extracted with potassium oxalate, isopropanol, ether and n-hexane solvents. The organic solvent with the pesticide residue is dissolved in benzene and passed through an alumina column before determination by gas liquid chromatography using a thermionic detector. The method was validated by EPA: analysis of fortified milk samples indicated recoveries of 80% and 88% at the 2.5 ppb level, and of 90% to 102% at the 5.0 ppb level. The sensitivity of the method is 0.5 ppb for milk fat.

The above methods have been validated, have adequate specificity, and are satisfactory for enforcement purposes.

d. Residue Data

Field residue data for dialifor should reflect the registered use with regard to application rate, mode of application, number and timing of treatments, formulations used, and geographical areas represented.

Because the oxygen analog may have an increased cholinergic potency, it is important to establish the levels of this oxon likely to be found in the combined residues on agricultural crops.

Some data were available to assess the proportions likely to be found in these crops. Residues of the oxygen-analog were determined in 52 selected samples of apples, orange peels, orange oil, orange (by-product dried) pulp, peaches, grapes, cottonseed, potatoes, and soil, using the TLC-enzyme inhibition procedure previously described. Residues of dialifor were determined by a GLC procedure (Eastmen, 1968?, 00002027).

Residues of the oxygen analog were found in almost every sample containing the parent compound, dialifor, and ranged up to 0.13 ppm (except for higher values of 0.45 ppm and 0.60 ppm in orange oil due to concentration and processing). Of the 52 samples, only three contained an oxygen analog residue exceeding 10% of the combined residues (e.g. 10.2%, 12.5%, and 17.2%; the last value is derived from inconsistent and questionable data). The preponderance of values show that the oxygen analog represents up to 12.5% of the combined residue of dialifor per se and dialifor-oxon. Previously this value had been rounded off to 10%.

If dialifor alone is determined, the combined residue residue can be calculated as follows:

$$\frac{\text{ppm dialifor}}{0.875} = \text{ppm combined residue}$$

The stability of dialifor residues during storage were also considered. Fortified acetone extracts of orange peels were reanalyzed after intervals of 1 to 5 months. The analytical data show that residues of dialifor persist unchanged in frozen extracts for periods of up to 25 weeks. For apple extracts they are stable up to 43 weeks (Hercules, 1968?, 00002032). These data are considered adequate for the crops discussed in this Standard.

Pecans

The directions for use of dialifor emulsifiable concentrates on pecans call for a) foliar application up to shuck split, b) single or multiple spray applications at a maximum rate of 0.45 lb ai/100 gallons (not to exceed 5.4 lb ai/acre/application), and c) different frequencies of application depending upon the type of pest to be controlled.

The available residue data for pecans (J.J. Ford, 1969, 00001990) reflect 3 single 0.5 lb ai/100 gallon spray applications to foliage of 10 pecan trees at 2-week intervals in Albany, Georgia. The interval between last spray and harvest was 35 days. Nut samples were analyzed by either a surface stripping analysis or nut-meat analysis. The regulatory method I (PAM Vol. II), slightly modified, was used to detect dialifor residues on these samples. The reported residue stripped from the pecan surface ranged from 0.006 ppm to 0.016 ppm with anaverage of 0.009 ppm. Crop blanks are reported as 0.000 ppm (sensitivity of this method is 0.004 ppm). The residue in the edible nut-meats averaged 0.005 ppm based on the analysis of 10 samples. Crop blanks are reported as 0.003 ppm (method sensitivity 0.003 ppm).

Additional data for residues of dialifor in pecans were presented (J.J. Ford, 1972, 00002130). A total of 33 samples from 6 tests located in 3 different states were analyzed. An average of 16 to 17 trees were sprayed to run-off with emulsions at concentrations of 0.5 lb to 1 lb of ai/100 gallons. The number of applications ranged from 2 to 6. The intervals between last spray and harvest varied from 14 to 121 days. The maximum residue in the nut-meats was less than 0.005 ppm, the detection limit of the analytical method used.

Unshelled nuts (meat plus shell, but excluding the husk) showed a maximum residue of 0.016 ppm at 35 days PHI (Ford, 1969, 00001990). Therefore, the shell is not a potential source of contamination of the nut-meat. Adequate recovery (120%) at 0.005 ppm fortification level was cited. The only real residue found on pecans was on the husk or shuck, but a tolerance is not required for the shuck because it is not used as animal feed or human food.

The submitted residue data are adequate to support a 0.01 ppm tolerance for combined residues of dialifor and dialifor-oxon in pecans. Data on levels of dialifor-oxon in pecans are not required due to the low levels of combined residues reported.

Citrus Fruits and Processed Citrus Products

Oranges

Use directions for the application of dialifor on oranges call for foliar spray applications up to seven days before harvest (PHI). Several kinds of applications are offered: single yearly applications at a maximum rate of 0.45 lbs/100 gallon and at a mimimum rate of 0.113 lbs/100 gallons, or double yearly applications at a maximum rate of 0.36 lbs/100 gallons and at a minimum rate of 0.113 lbs/100 gallons.

Summary Table

Crop	Rate of Application	PHI	Residues	Reference
Valencia Oranges	6-double .25 lb ai/100 gal. (second application 3 months after first)	3 days 7 days 84 days	.7 ppm .69 ppm .37 ppm	Hercules, 1968, 00002032
	6-double .5 lb ai/100 gal. (second application 3 months after first)	3 days 7 days 84 days	1.3 ppm 1.2 ppm .61 ppm	"

Residue data obtained for these samples indicate a half-life of approximately 70 days at each of the two dosages studied. The decrease of residue with time is a function of weathering and of growth of mature fruits. Since, in this study, mature oranges were used, the residues found represent the maximum that would occur from the given applications. In addition, the study confirms that dialifor residues are not confined entirely to the peel of the orange, because the residue does not penetrate into the edible portion of the fruit even after exposure for periods of 12 weeks. The reported residues are calculated values based on analyses of peel fractions and adjustment to the whole fruit basis. Crop blanks were reported as 0.0 ppm (sensitivity of the method, 0.01 ppm).

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Pineapple Oranges	3@ .29 lb ai/100 gal. (first application at petal fall; final 5 months later)	3 days 84 days	1.4 ppm .59 ppm	Hercules, 1969?, 00001967
	3@ .5 lb ai/100 gal. (first application at petal fall; final 5 months later)	3 days 84 days	1.9 ppm 1.1 ppm	Hercules, 1968?, 00001968 Hercules, 1969?, 00001969

The analyses reported above were done at Pesticide Research Laboratory, University of Florida. The studies utilized three instead of the maximum of 2 treatments. However, in each case where applications were made, the first was made at petal fall when the fruit had just started to form. Thus for this evaluation we can equate the treatments in the residue studies to the recommended dual applications.

The residue data obtained from pineapple oranges indicated a half-life of 80 to 85 days. The residue levels reported are on a whole fruit basis. Recovery studies with pineapple orange peel samples showed an average value of 90.6% at a 5.83 ppm dialifor fortification level. These data are not in perfect agreement with the residue levels in Hercules, 1968, 00002032, because the reported residue values show a maximum level of 1.2 ppm at 7 days after the last application at the higher spray rate in 00002032.

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Valencia Oranges	4 single @ 5 oz./100 gal. water/full coverage spray	3 days 125 days	4.9 ppm .7 ppm	Westlake, 1971, 05001345
	4 single @ 10 oz./100 gal. water/full coverage spray	3 days 125 days	6.7 ppm 1.4 ppm	
	4 single @ 5 lb ai/50 gal. water/acre	3 days 125 days	9.1 ppm 2.5 ppm	
	4 single @ 10 lb ai/50 gal. water/acre	3 days 125 days	18.5 ppm 4.3 ppm	
	4 double @ 5 lb ai/50 gal. water/acre	3 days 125 days	14 ppm 3.6 ppm	
	4 double @ 5 oz./100 gal. water/full coverage spray	3 days 125 days	7.4 ppm 2.4 ppm	
	1 single @ 5 oz./100 gal. water/full coverage spray	7 days	1.2 ppm	
	1 single @ 10 oz./100 gal. water/full coverage spray	7 days	2.4 ppm	

Decline curves were submitted and showed a residue half-life of 60 days for the concentrated spray (5 lb and 10 lb ai/50 gallon water acre), and a residue half-life of 40 days for the dilute spray (5 oz. and 10 oz./100 gallon water/full coverage spray). The difference was attributed to the two types of applications (blast spray for concentrated and manual for the diluted).

Analysis of the pulp of the samples collected at 7, 21, 42, 75, and 125-day intervals showed no detectable residue, showing that the pesticide did not penetrate into the pulp. Recovery data were good for the determination of residues in rind and pulp of oranges using the GLC method developed by Hercules (J.J. Ford, 1968, 00002005). At a .5 ppm fortification level the orange pulp gave a recovery of 91 ± 9%. At a 3 ppm fortification level the orange rind gave a recovery of 105 ± 3%. Good recoveries of 110% were also obtained for ground rinds fortified with 3 ppm.

Summary Table

Crop	# & Rate of Application	PHI	Residue	Reference
Valencia Oranges	Single .5 lb/100 gal. spray	3 days	1.7 ppm	Reinking, 1973?, 00002138
		7 days	1.8 ppm	
		14 days	1.7 ppm	
		28 days	1.4 ppm	
		56 days	1.2 ppm	
		84 days	.88 ppm	

Blanks are reported as 0.0 ppm. Sensitivity of a modification of the GLC method developed by Hercules was 0.01 ppm.

Grapefruit

The directions for application of dialifor to grapefruit are basically the same as those for application to oranges. However, when double application is called for, one must be done in the spring (post blossom) and the other in the summer.

Summary Table

Crop	# & Rate of Application	PHI	Residue	Reference
Ruby Grapefruit	3@ .29 lb ai/100 gal.	3 days	.64 ppm	Hercules, 1969?, 00001967
		84 days	.62 ppm	
	3@ .5 lb ai/100 gal.	3 days	1.2 ppm	Hercules, 1968?, 00001968 Hercules, 1969?, 00001969
		84 days	1.1 ppm	
Ruby Grapefruit	Single @ .5 lb/100 gal. spray	3 days	1.8 ppm	Reinking, 1973?, 00002138
		7 days	1.9 ppm	
		14 days	1.8 ppm	
		28 days	1.7 ppm	
		56 days	1.6 ppm	
		84 days	1.4 ppm	

Recovery studies with grapefruit peels (00001967, 00001968, 00001969), showed an average value of 98.8% at a 2.9 ppm dialifor fortification level. All blanks were reported as 0.0 ppm. These values are in agreement with reported levels in oranges in Hercules, 1968, 00002032.

Within the limits of experimental error, residues of dialifor in grapefruit did not change from the third day after the last treatment until the final sampling at the 84th day. Even at the higher rate they were below the established tolerance of 3 ppm for combined residues of dialifor and its oxon in citrus fruits.

Lemons

The directions for use of dialifor in on lemons call for foliar applications up to seven days before harvest. Several types of application are offered, single and double (spring and summer spray), at a maximum rate of 0.45 lb ai/100 gallons and a minimum rate of 0.113 lb ai/100 gallons.

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Lemons	3@ .29 lb ai/100 gal.	3 days 65 days	.25 ppm .08 ppm	Hercules, 1969?, 00001967
	3@ .5 lb ai/100 gal.	3 days 65 days	.38 ppm .24 ppm	Hercules, 1968?, 00001968 Hercules, 1969?, 00001969

Recovery studies with lemon peels showed an average value of 91.73% at a 1.41 ppm dialifor fortification level. All blanks were reported as 0.05 ppm.

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Lemons	Single 10 oz. ai/100 gal.	6 days	1.53 ppm	Westlake, 1971, 05001345

Analysis of the pulp of the samples collected at 7, 21, 42, 75, and 125-day intervals showed no detectable residue, showing that the pesticide did not penetrate into the pulp. Recovery data were good for the determination of residues in rind and pulp using the GLC method developed by Hercules (J.J. Ford, 1968, 00002005). At a .5 ppm fortification level the lemon pulp gave a recovery of 99 ± 19%. At a 3 ppm fortification level the lemon rind gave a recovery of 110 ± 9%. Good recoveries of 110% were also obtained for ground rinds fortified with 3 ppm dialifor.

Citrus Pulp, Molasses, and Citrus Oil

Two pilot plant studies reported in 00002033 and 00001966 show residue data for orange and grapefruit by-products such as juice, citrus oil, molasses, and dried citrus pulp. Molasses and dried citrus pulp constitute part of commercial cattle feed and deserve special consideration. Valencia Oranges and Ruby Red Grapefruit were commercially processed at Lake Alfred, Florida.

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Valencia Oranges	.25 lb ai/100 gal.	21 days	RAC: .52 ppm Juice: None found Chopped Peels: .76 ppm Molasses: .16 ppm Dried Citrus Pulp: 2.7 ppm Orange Oil: 6.4 ppm	Hercules, 1969, 00002033 Hercules, 1971?, 00001966
	.5 lb ai/100 gal.	21 days	RAC: .86 ppm Juice: None found Chopped Peels: 1.6 ppm Molasses: 1.3 ppm Dried Citrus Pulp: 5.5 ppm Orange Oil: 12 ppm	"
Ruby Red Grapefruit	.25 lb ai/100 gal.	20 days	RAC: .55 ppm Juice: None found Chopped Peels: .85 ppm Molasses: .14 ppm Dried Citrus Pulp: 2.6 ppm Grapefruit Oil: 20 ppm	"
	.5 lb ai/100 gal.	20 days	RAC: 1.2 ppm Juice: None found Chopped Peels: 1.6 ppm Molasses: .25 ppm Dried Citrus Pulp: 6.1 ppm Grapefruit Oil: 37 ppm	"

In processing unwashed oranges to dry pulp, the concentration factor was 2.7/0.52 = 5.1 at the lower spray rate and 5.5/0.86 = 6.4 at the higher spraying rate.

In processing grapefruit to dry pulp, the conversion factor was 2.6/0.55 = 4.7 at the lower spraying rate and 6.1/1.2 = 5.1 at the higher spraying rate.

These studies show concentration factors from unwashed orchard fruit to dried citrus pulp of from 4.7-6.4. When the feed item is reconstituted with molasses at 2/3rd dried pulp and 1/3rd molasses, the maximum in the reconstituted feed would be:

$$\frac{2}{3}(6.4 \times 3) + \frac{1}{3} \times 1.3 = 13.2 \text{ ppm dialifor}$$

Therefore, a food additive tolerance is needed, and a level of 15 ppm for combined residues of dialifor and its oxygen analog in dried citrus pulp is considered appropriate.

The highest residues were found in citrus oil samples, amounting to 6.4 ppm to 12 ppm for orange oil and 20 ppm to 37 ppm for grapefruit oil. This is because the oil fraction represents the more solubilizing vehicle for the pesticide residue, as well as being the smallest fraction of the original fruit. The results of both studies are in agreement. A tolerance is needed for citrus oil.

In the recovery of the citrus oil, the following concentration factors were observed: 6.4/0.52 = 12.3; 12/0.86 = 14.0; 20/0.55 = 36.4 and 37/1.2 = 30.8. The maximum level likely to occur would be 36.4 x 3 = 109.2 ppm combined residue. Therefore, a Food Additive tolerance of 110 ppm is considered appropriate for combined residues of dialifor and its oxygen analog in citrus oil.

Grapes

The directions for use of dialifor on grapes call for two foliar spray applications per season, one before and one after the shotberry stage, at a rate of 0.9 lbs. ai/15-120 gal. water/acre (35 days PHI are indicated). The label limits use to California.

Summary Table

Crop	# & Rate of Application	PHI	Residue	Reference
Thompson Seedless Grapes	3 double @ .5 lb ai/acre	34 days	.54 ppm	Ford, 1970, 00001984
		48 days	.36 ppm	
		62 days	.23 ppm	
	3 double @ 1 lb ai/acre	34 days	1.2 ppm	"
		48 days	.7 ppm	
		62 days	.94 ppm	
Concord Grapes	1 double @ 1 lb ai/acre	78 days	2.2 ppm	"

Crop blanks are quoted as 0.00 ppm. Sensitivity of the method is 0.2 ppm.

Additional residue data from two decline studies and two terminal residue studies from San Joaquin Valley, California were reported. Decline studies:

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Thompson Seedless Grapes	1-3 @ 1 lb ai/acre	0 days	1.27 ppm	Ford, 1972, 00002127
		7 days	.26 ppm	
		14 days	.76 ppm	
		28 days	.68 ppm	
		56 days	.63 ppm	
		112 days	.08 ppm	
	1-3 @ 2 lbs ai/acre	0 days	2.63 ppm	"
		7 days	1.79 ppm	
		14 days	2.46 ppm	
		28 days	1.65 ppm	
		56 days	2.26 ppm	
		112 days	.25 ppm	

Blanks were quoted as 0.0 ppm and the sensitivity of the method was 0.01 ppm.

Terminal residue studies:

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Carignane & Emperor	Single @ 1 lb ai/acre	2 days	1.8 ppm	Ford, 1972, 00002127
		7 days	.86 ppm	
		13 days	.80 ppm	
		27 days	.41 ppm	
		48 days	1.0 ppm	
		68 days	.42 ppm	
	Single @ 2 lbs ai/acre	2 days	1.8 ppm	"
		7 days	1.1 ppm	
		13 days	.87 ppm	
		27 days	.53 ppm	
		48 days	.59 ppm	
		68 days	.37 ppm	

More recent residue data from a field study conducted in California have been submitted.

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Grapes	3 @ 1 lb ai/acre	35 days 40 days	.67 ppm .83 ppm	Hercules, 1973, 00002117
Grapes	1 @ 1 lb ai/acre	34 days	1.2 ppm	Hercules, 1969?, 00001994

The data presented on residues of dialifor in or on grapes demonstrate that the established 1 ppm tolerance for combined residues of dialifor and dialifor oxon on or on fresh grapes will not be exceeded when dialifor is applied as directed (with a 35 day preharvest interval). Only one sample showed a maximum residue value of 1.2 ppm.

The decline curves of residues on Carignane and Emperor grapes showed little initial deposits from two sprays of about 2.0 ppm at the rate of 2 lbs. ai/acre, a steady decline for 25-30 days to about 0.4 ppm, and finally a leveling off with little additional loss until harvest. The pattern of residue decline coincides with the growth of the grapes, there being practically no growth dilution over the last 20-25 days before harvest.

Sprays of the final application are the ones that affect the value of the final residue. Recovery studies on grapes indicate an average value of 93% at a fortification level ranging from 0.3 ppm tp 0.5 ppm. The tolerance of 1 ppm for combined residues of dialifor and its oxygen analog is therefore considered adequate for fresh grapes.

Raisins and Raisin Waste

The recommended treatment to harvest interval for raisins is 60-70 days in place of 35 days for fresh grapes. Raisins are, in fact, harvested several weeks later than the fresh fruit because they need additional time to develop their high sugar content.

Residue studies of dialifor levels found on raisins made from dialifor treated grapes are summarized below:

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Thompson Seedless Raisins[1]	1 @ .5 lb ai/acre 1 @ 1 lb ai/acre	62 days 62 days	.37 ppm 1.2 ppm	Ford, 1970, 00001984
Thompson Seedless Raisins[2]	1 @ .5 lb ai/acre 1 @ 1 lb ai/acre	62 days 62 days	.30 ppm 1.2 ppm	"

1- Unprocessed raisins, field dried, fumigated with methyl bromide and cured.

2- Processed raisins, field dried, washed, de-stemmed, and sorted for size.

The concentration factor was 1.44 at both application rates.

Summary Table

Crop	# & rate of Application	PHI	Residues	Reference
Raisins	Double @ 1 lb ai/acre	41 days 71 days	1.4 ppm 1.6 ppm	Ford, 1972, 00002127
	Single @ 3 lbs ai/acre	49 days	4.3 ppm	

The average concentration factor was quoted as 3.2, ranging from 1.8 to 4.3, respectively; however, that for Thompson seedless grapes (average of 2) was 4.1.

Residue data from a 1973 field study conducted in California are presented below and support a concentration factor of 1.6 from grapes to processed raisins:

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Raisins	3 @ 1 lb ai/acre 2 @ 1 lb ai/acre	35-40 days 70 days	.98 ppm .2 ppm	Hercules, 1973, 00002117

Owing to the effect of processing, the concentration factor is considered to be 1.6, and the maximum of combined residues in raisins is 1.6 ppm. The established Food Additive Tolerance of 2 ppm is therefore appropriate for combined residues of dialifor and its oxygen analog in or on raisins.

Raisin waste, which contains imperfect raisins and associated trash obtained as a by-product of raisin production, was found to contain up to 2.8 ppm of dialifor. The raisins, containing an average residue of 1.2 ppm, were the source of the waste, giving a concentration factor of 2.3. Fresh grapes, bearing residues of dialifor at 1 ppm, could therefore yield processed raisins at 2 ppm and raisin waste at 4.6 ppm combined residues.

The Food Additive Tolerance of 10 ppm for combined residues of dialifor and its oxygen analog in raisin waste is more than ample. However, because of the variation of residues in trash, a change (reduction) in the level of this tolerance is not recommended.

Grape Juice and Pomace

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Emperor	Single @ 1 lb ai/acre	Unknown	Juice: .005 ppm	Ford, 1972,
Grapes	Single @ 1.8 lb ai/acre	Unknown	Juice: .008 ppm	00002127

The dialifor residue on these grapes was about 0.4 ppm, indicating that the residue detected in the juice was 1/50 of that in fresh grapes. Juice of grapes bearing a dialifor residue of 1.0 ppm (tolerance level) would therefore contain no more than 0.02 ppm.

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Grapes	1 lb ai/acre	68 days	Pomace: .57 ppm	Ford, 1972,
	1.8 lbs. ai/acre	68 days	Pomace: 1.4 ppm	00002127

Based on the residues on the fresh grapes estimated from the decline curve, the concentration factors for grapes to wet pomace are the same as those for grapes to unprocessed raisins, 4.3. Because 27% of the weight of the fresh grapes was converted to the pomace remaining after juice extraction, a concentration factor of 1/0.27 = 3.7 would be expected if the residue on the fresh fruit were entirely retained in the pomace. For Thompson Seedless Grapes, the concentration factor is 4.1.

Thus, the combined residue of dialifor and its oxon in wet grape pomace is considered to be about 5 ppm.

In 00001984 a concentration factor of up to 4 from wet grape pomace to dried grape pomace can be calculated. Thus, the maximum overall concentration factor from fresh grapes to dried pomace is 1 x 4.3 x4 = 17.2.

Based on the tolerance in grapes of 1 ppm, the Food Additive tolerance of 20 ppm for combined residues of dialifor and its oxygen analog is appropriate for dried grape pomace.

Apples, Pomace, and Juice

The directions for use on apples call for multiple foliar spray applications (no more than 6) up to 60 days before harvest in states bordering on or east of the Mississipi River. Two types of application are recommended: multiple .75 and .5 lbs a.i./100 gallons water in spray applications, using the 50% W.P. formulation. The most commonly used method of application is to point of runoff, and the maximum amount actually applied per acre is indicated as 2.26 lbs. dialifor/acre (at the .75 lb application level) and 1.5 lbs. dialifor/acre (at the .5 lb application level).

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Apples Pennsylvannia	6 50% WP @ .5 lb ai/100 gal.	41 days	1.0 ppm	Hercules, 1968, 00002034
Apples Wisconsin	6 4% EC @ 1 lb ai/100 gal.	27 days	1.7 ppm	
	6 4% EC @ 1.5 lb ai/100 gal.	27 days	4.3 ppm	
Apples New York	Multiple 50% WP @ .5 lb ai/100 gal.	37 days	.85 ppm	
Apples England	1 50% WP @ .25 lb ai/100 gal.	80 days	.07 ppm	
	1 50% WP @ .5 lb ai/100 gal.	80 days	.01 ppm	
	1 50% WP @ 1 lb ai/100 gal.	80 days	.21 ppm	

Crop blanks were 0.00 ppm and the sensitivity of the method was 0.01 ppm.

Eight studies with field apples, seven in Eastern States and one in Western States (Washington), showed the following:

Summary Table
Terminal Residue Studies

Location	# & Rate of Application	PHI	Residues	Reference
Wilmington Delaware	9 EC @ .5 lb ai/100 gal.	29 days	1.10 ppm	Ford, 1969, 00001961
Geneva New York	7 EC @ .5 lb ai/100 gal.	32 days	2.5 ppm	
Winchester Virginia	2 EC @ .5 lb ai/100 gal.	46 days	1.3 ppm	
Highlands New York	9 EC @ .75 lb ai/100 gal.	36 days	1.2 ppm	
Geneva New York	7 EC @ .75 lb ai/100 gal.	32 days	2.9 ppm	
Hickory Corner Michigan	9 EC @ 1 lb ai/100 gal.	56 days	1.0 ppm	
	9 EC @ 1.5 lb ai/100 gal.	56 days	1.6 ppm	

Summary Table
Decline Studies

Location	# & Rate of Application	PHI	Residues	Reference
Arendtsville Pennsylvania	6 WP @ .5 lb ai/100 gal.	0 days	3.4 ppm	Ford, 1969, 00001961
	"	7 days	3.2 ppm	
	"	14 days	1.6 ppm	
	"	28 days	1.1 ppm	
	"	52 days	.66 ppm	
	6 WP @ 1 lb ai/100 gal.	0 days	4.8 ppm	
	"	7 days	4.4 ppm	
	"	14 days	2.2 ppm	
	"	28 days	1.4 ppm	
	"	52 days	1.1 ppm	
Yakima Washington	3 EC @ 1 lb ai/100 gal.	0 days	7.8 ppm	
	"	7 days	7.5 ppm	
	"	14 days	4.9 ppm	
	"	21 days	4.6 ppm	
	"	28 days	4.9 ppm	
	"	42 days	3.2 ppm	
	"	58 days	3.2 ppm	

Control samples showed no detectable residues. The decline curves from the Pennsylvania study and the Washington study show a very similar rate of decline in residues, with a change in slope at 32 and 28 days respectively. The two corresponding half-lives for dialifor calculated from the second half of the decline curves were 40 days and 65 days respectively. Growth dilution was found to be the principal factor in the reduction of dialifor residues on apple fruit in Washington.

In Pennsylvania, where the wettable powder was used, additional losses attributed to climactic factors were observed. Another cause of higher residues was the method of application (to full runoff). This study shows that dialifor is a persistent pesticide because little residue is lost after the initial period. It also shows that the 50% wettable powder gives lower residues than the emulsifiable concentrate, and, that in the western states, the residues are higher. Recoveries of dialifor ranged from 88% to 94% at .5 to 2.5 ppm fortification levels.

Twenty additional studies on field apples were submitted:

Summary Table

Location	# & Rate of Application	PHI	Residues	Reference
Yakima, WA	6 WP @ .5 lb ai/100 gal.	63 days	1.4 ppm	Ford, 1972, 00001993
Winchester, VA	"	"	.43 ppm	
Arendstville, PA	"	"	1.16 ppm	
Hancock, MD	"	"	.18 ppm	
Fennville, MI	"	"	1.44 ppm	
Geneva, NY	"	"	1.10 ppm	
Winchester, VA	6 WP @ 1 lb ai/100 gal.	63 days	.77 ppm	
Yakima, WA	"	"	2.04 ppm	
Arendtsville, PA	"	"	2.32 ppm	
Fennville, MI	"	"	2.3 ppm	
Geneva, NY	"	"	1.5 ppm	

These studies confirm that dialifor forms a persistent residue on apples, and that its half-life ranges from 17 days to more than 70 days for the wettable powder formulation, with an average of 46 days.

Doubling the proposed rate does not result in a proportional residue increase. The data are adequate to support the established tolerance of 1.5 ppm for combined residues of dialifor and its oxon in or on fresh apples at the recommended application rate and preharvest interval.

Apple Juice and Pomace

Summary Table

Crop	# & Rate of Application	PHI	Residues	Reference
Apples	50% WP @ 1 lb ai/100 gal.	Unknown	RAC: .63 ppm Juice: .04 ppm	Ford, 1972, 00001993

The magnitude of the residue detected in the juice was less than 1/10 the residue on the whole fruit. Fortification and recovery experiments for the juice samples yielded an average recovery of 99% over a fortification range of 0.025 to 0.20 ppm.

The apples were processed in small quantities to produce apple pomace. Data reported show that there are variable concentrations between the harvested apples and wet pomace, ranging from 1.6-3.8. When apples are pressed for juice the yield is usually 22 or 25% wet pomace by weight, the concentration factor being 4.5 or 4, assuming no losses. This is in reasonably good agreement with the highest observed factor of 3.8. Using this observed factor, the combined residues of dialifor and its oxon in wet apple pomace is 1.5 x 3.8 = 5.7 ppm (6 ppm). The factor between wet and dried pomace was not determined experimentally. However, it has been calculated with wide variations up to 7.5.

The usual concentration factor between fresh fruit and dried pomace is 25. With this factor, the residue in dried pomace, given the established tolerance of 1.5 ppm for residues in apples, is 1.5 x 25 = 37.5 ppm for combined residues of dialifor and its oxon. Thus, the Food Additive tolerance of 40 ppm in dried apple pomace is considered appropriate.

Animal Feeds Using Citrus, Apple and Grape By-Products

Wet and dried apple pomace, dry citrus pulp, dried grape pomace and raisin waste are sometimes utilized as components of cattle feed. Dried grape pomace is also fed to poultry. Hercules (1972?, 00002125) reports the maximum percentages that are incorporated in the total animal diet and the accompanying contributions can be calculated as follows:

Product	Maximum as Combined Residues	Maximum Payment in Total Diet	Maximum Combined Residues Contributed to Total Diet
Citrus Pulp dry	15 ppm	30% (cattle)	4.5 ppm
Apple Pomace wet	6 ppm	30% (cattle)	1.8 ppm
Apple Pomace dry	40 ppm	50% (cattle)	20.0 ppm
Grape Pomace wet	6 ppm	50% (cattle)	3.0 ppm
Grape Pomace dry	20 ppm	20% (cattle)	4.0 ppm
		5% (poultry)	1.0 ppm
Raisin Waste	10 ppm	10 % (cattle)	1.0 ppm

Meat, Milk, Poultry and Eggs

It is a well-known agricultural practice to feed dry apple pomace, dry citrus pulp and dry grape pomace to farm animals such as cattle, goats, sheep and poultry. The following studies were conducted to determine whether or not residues would transfer from feed to meat, milk, poultry and eggs.

No residue studies are reported for treated cover crops in fruit orchards where cattle may be grazaed.

There are no registered uses for dialifor on primary forage crops.

Milk

A study on three dairy cows fed at a rate of 45 ppm dialifor for three weeks (9 times the normal feeding level). Residues in whole milk were found to be dialifor per se and ranged from 0.001 to 0.013 ppm. The average value for three cows throughout the period was 0.0008 ppm. One value of 0.035 ppm was considered aberrant and was discarded. Analyses of the milk samples were performed with Regulatory Method III, PAM Vol. II. Recoveries of milk samples fortified at 8 to 41 ppb were 90%. Sensitivity of the method is 1-2 ppb. For milk containing 4% fat, 0.01 ppm dialifor is equivalent to $\frac{0.01 \times 100}{4}$ = 0.25 ppm on a milk fat basis.

Milk was also analyzed in a feeding experiment performed on a Holstein cow that was fed dialifor daily at a level of 5 ppm for a period of 4 days (St. John and Lisk, 1971, 00002268, 05001830). Samples of milk from this animal were collected during the feeding period and for 6 days thereafter. No residues of dialifor or its oxygen analog were found in any of these samples, analyzed by a slightly modified version of the method mentioned above (electron affinity gas chromatography was the detection system). Samples of milk fortified with 0.05 ppm of dialifor gave a recovery of 80-92%. Samples of milk fortified with 0.05 ppm of the oxygen analog gave a recovery of 62-78%. Sensitivity of the method was 0.01 ppm.

The maximum amount of dialifor residues which can be transferred from different animal feeds to milk fat are presented in the following table from 00002022:

Product	Dietary Dialifor Level	Residues in Milk	Maximum Dialifor Contributed	Milk Fat Basis
Dry Citrus Pulp	45 ppm	0.01 ppm	4.5 ppm	.025 ppm
Wet or Dry Apple Pomace	45 ppm	0.01 ppm	20 ppm	.11 ppm
Wet or Dry Grape Pomace	45 ppm	0.01 ppm	4.0 ppm	.022 ppm
Raisin Waste	45 ppm	0.01 ppm	1.0 ppm	.05 ppm

The tolerance of 0.15 ppm for residues of dialifor in milk is adequate.

Meat

In a feeding study (Ford, 1969, 00002024) three beef calves were maintained on a dry diet containing 60 ppm of dialifor administered for different intervals of time; 2, 4, and 8 weeks for each calf. A fourth calf served as the control. At the end of the feeding period, the animals were sacrificed, and the tissues were analyzed. Lean muscle, liver, kidney and fat tissues were analyzed by TLC and gas chromatographic procedures. Regulatory method II was used. Sensitivity of the method is 0.005 ppm.

All residues except those in liver and fat were said to be non-detectable (<0.1 ppm). Residues in the liver of the animals sacrificed at 4 and 8 weeks ranged from 0.1 to 0.3 ppm. However, 1 ppm was found in the liver of the animal sacrificed at 2 weeks. The latter value is not typical and was probably influenced by illness contracted by the calf. As to fat, maximum residues of 0.4 ppm occurred. All tissues were also analyzed by TLC for residues of oxygen analog but no significant quantities were reported. In two samples of liver and fat tissues the residues were close to the method sensitivity (3-5 ppb).

In order to obtain additional information, 9 beef calves were fed 0, 2.0, and 4.0 ppm of dialifor (Taylor, 1969, 00002038). The animals were killed and samples of tissues were taken at 12 and 28 days. No dialifor was detected in liver, kidney, fat and lean muscle tissues taken at 12 days, and residue values in the range of the sensitivity of the method (2-3 ppb) were detected in 5 of the 24 tissue samples taken at 28 days. No dialifor was detected in the remaining 19 tissue samples. Recovery was uniformly greater than 87% for the method used.

Based on the above data, the maximum which can be transferred from different feeds to animal tissues can be calculated:

Product	Contribution to Total Diet	Transfer to: Liver	Fat
Dry Citrus Pulp	4.5 ppm	.023 ppm	.03 ppm
Dry Apple Pomace	20 ppm	.1 ppm	.13 ppm
Dry Grape Pomace	4.0 ppm	.02 ppm	.027 ppm
Raisin Waste	1.0 ppm	.0005 ppm	.0007 ppm

The tolerance of .15 ppm for residues in meat, fat and meat by-products of cattle, goat and sheep is adequate.

Poultry

Residues in poultry and eggs are determined in an 8-week feeding study using 18 laying hens divided into 6 groups of 3 birds each (Ford, 1972, 00002129). Two groups were fed dialifor at 3.7 ppm, 2 groups at 11.2 ppm and 2 groups served as controls. Egg samples were collected every 96 hours, shelled, blended and analyzed. They showed no residue. One bird from each group was sacrificed after 4 weeks and tissue samples were analyzed. The remaining birds were sacrificed at the end of the 8-week period. Method II with a sensitivity of 5 ppb was used. Average recoveries of 90% are quoted at the 3 microgram dialifor fortification level.

The available data are contradictory because some controls showed apparent residues of dialifor, indicating contamination of the feed. In addition, there was no apparent dose-response; a considerable percentage of the birds showed no detectable residues regardless of dose level. Highest net residues were 0.05 ppm in several of the organs. These data show that trace residues can be transferred to the tissues of poultry and are covered by the tolerances of 0.05 ppm for poultry and 0.01 ppm for eggs.

Current Tolerances

Tolerances have been established in the United States as follows for residues of dialifor and its oxygen analog pursuant to 40 CFR 180.326 (FR 39:9964, March 15, 1974; and FR 39:13073, April, 1974):

at:	in:
3 ppm	or on citrus
1.5 ppm	or on apples
1 ppm	or on grapes
0.15 ppm (N)	meat, fat and meat by-products of cattle, goat and sheep
0.15 ppm (N)	milk fat (reflecting negligible residues in whole milk)
0.05 ppm (N)	meat, fat, and meat by-products of poultry
0.01 ppm (N)	eggs
0.01 ppm (N)	pecans

N= negligible residue tolerance

Permanent Food Additive Tolerances have been established for residues of dialifor and its oxygen analog pursuant to 21 CFR 123.130 and 561.140:

at:	in:
40 ppm	apple pomace, dried
15 ppm	citrus pulp, dried
20 ppm	grape pomace, dried
2 ppm	raisins
10 ppm	raisin waste

Theoretical Maximum Residue Contribution

The TMRC (Theoretical Maximum Residue Contribution) of dialifor to the human diet is currently .265 mg/day.

Crop	Tolerance	Food Factor	mg/day (1.5 kg)
Citrus Fruits	3.0 ppm	3.81	0.17154
Apples	1.5 ppm	2.53	0.05693
Grapes (inc. raisins)	1.0 ppm	0.49	0.00736
Meat (red)	0.150 ppm	10.81	0.02433
Milk & Dairy Products	0.006 ppm	28.62	0.00258
Poultry	0.050 ppm	2.94	0.00221
Eggs	0.010 ppm	2.77	0.00042
Pecans	0.010 ppm	0.03	0.00000

TMRC: 0.2654 mg/day (1.5 kg)

Codex Tolerances

Maximum residue limits in the form of tolerances have been recommended by the Codex Alimentarius Commission for residues of dialifor and its oxygen analogue (sic), expressed as dialifor. Because these recommendations are currently in Step 8, this country can expect a request to accept them. These are:

Maximum Residue Limit (mg/kg)	Type of Limit	
at		in
40	T	Apple Pomace (Dried)
2	T	Apples
.2 (carcase fat)	T	Cattle, Carcase Meat
3	T	Citrus Fruit
15	T	Citrus Pulp (dried)
.01*	T	Eggs
20	T	Grape Pomace (dried)
1	T	Grapes
.2 (fat basis)	T	Milk
2	T	Pears
.01*	T	Pecans
.05*	T	Poultry, Fat
.05*	T	Poultry, Carcase Meat
2	T	Raisins
.2 (carcase fat)	T	Sheep, Carcase Meat

* Level at or about the limit of detection.

Tolerances have been established in Canada as follows for residues of dialifor:

at	in
2.0 ppm	citrus fruits, raisins
1.5 ppm	apples
1.0 ppm	grapes
.1 ppm	pecans

When the Codex MRL's are advanced to Step 9 of the Codex approval process, the following changes in this country's tolerances will be implemented, toxicological considerations permitting:

Apples: increase the tolerance from 1.5 to 2.0 ppm

Meat, fat and meat byproducts of cattle (with or without goats) and sheep: increase the tolerance from .15 to .2 ppm

Milk Fat: increase the tolerance from .15 to .2 ppm

These changes would increase the TMRC from .265 to .295 mg/day.

Regulatory Incidents

No report was made of any action taken by FDA, even though dialifor is looked for; and none by APHIS (USDA).

C. Dialifor End-Use Formulations

1. Registration Requirements

For future registration of a product for use on a food or feed crop not covered by this Standard, the Agency must be provided with a petition for tolerance, a full range of data including a validated method for analysis of residues in or on the raw agricultural commodity, data on metabolism of dialifor in plants and (when appropriate) in animals, and residue data reflecting the proposed use of the pesticide on the crop.

CHAPTER VIII

ECOLOGICAL EFFECTS OF DIALIFOR

Ecological Effects Profile

Available information suggests that dialifor is no more than moderately toxic to wild waterfowl, very highly toxic to estuarine invertebrates, and low in toxicity to honey bees. Data on the toxicity of dialifor to non-target organisms is scant. The only valid studies available were a subacute dietary LC50 test on the mallard duck; a 96-hour LC50 test on two estuarine invertebrates (grass shrimp and mud crab); and contact and oral LD50 tests on honey bees.

The subacute avian dietary study contained sufficient information to characterize dialifor as no more than moderately toxic to wild waterfowl with no mortality occurring in mallard ducks feeding on 464 ppm. Excessive food rejection at higher dosages precluded calculation of an LC50 value.

The acute 96-hour LC50 toxicity studies on the estuarine grass shrimp and mud crab contained sufficient information to characterize dialifor as very highly toxic to estuarine invertebrates, with LC50 values of 3.56 ppb and 33.5 ppb respectively.

Laboratory studies on the honey bee contained sufficient information to characterize dialifor as generally low in oral (LD50: 29.2 ug/bee) and contact toxicity (LD50: 9.5 to 34.45 ug/bee).

Topical Discussions

Data on the effects of dialifor on non-target species are required due to the outdoor, terrestrial end-uses of products formulated from manufacturing-use dialifor.

Effects on Birds

Acute Toxicity

Avian acute oral LD50 data on either wild waterfowl or upland game birds are required. One study (Fletcher, 1972, 00002192) on the mallard duck was reviewed and found to be scientifically unsound, because dose levels resulting in regurgitation were not identified. The LD50 value was reported as 940 (752-1175) mg/kg.

This study was conducted by Industrial Biotest Laboratories. This study was reviewed in EPA's Laboratory Audit Program, and has been invalidated.

Subacute Dietary Toxicity

Waterfowl

Data on the subacute dietary toxicity of dialifor to mallard ducks were available. In a study completed by Beavers (Beavers, 1977, 00002139) the NEL (No Effect Level) was established as greater than 464 ppm. in mallard ducks. There is sufficient information to characterize dialifor as no more than moderately toxic to wild waterfowl. No mortality occurred at 464 ppm. Excessive food rejection at higher dosages precludes the calculation of the LC50 value. No additional data are required.

Upland Game Bird

Avian dietary LC50 data on one species of upland game bird are required. One study (Wolvin, 1969, 00002176) utilizing the bobwhite quail, was reviewed and was determined to be invalid because the birds tested were 9 weeks old rather than 10-17 days old (more sensitive age). The bobwhite dietary LC50 was reported as greater than 5620 ppm with some food rejection at all test concentrations.

This study was conducted by Industrial Biotest Laboratories. This study was reviewed in EPA's Laboratory Audit Program, and has been invalidated.

Chronic Toxicity

An avian reproduction study on one species of upland game bird (preferably the bobwhite quail) and one wild waterfowl (preferably the mallard duck) is required because the use of dialifor can result in repeated exposure. No avian reproduction data were available. These data are needed.

Effects on Fish

Acute Toxicity

Coldwater Fish

96-hour LC50 data on one species of coldwater fish are required. Two studies were available to assess the LC50 of dialifor in rainbow trout (Schoenig, 1966, 00002057; Shoenig, 1967, 00002058). LC50 values of 0.55 ppm and 1.08 ppm,respectively, were reported. Both of these studies were completed by Industrial Biotest Laboratories. These studies have been reviewed in EPA's Laboratory Audit Program, and have been invalidated. Testing is needed.

Warmwater Fish

96-hour LC50 data on one species of warmwater fish are required. Two studies were available to assess the LC50 of dialifor in bluegill sunfish (Schoenig, 1966, 00002057; Schoenig, 1967, 00002058). LC50 values of 0.064 (0.058-0.070) and 0.0224 ppm, respectively, were reported. Both of these studies were completed by Industrial Biotest Laboratories. These studies have been reviewed in EPA's Laboratory Audit Program, and have been invalidated. Testing is needed.

Chronic Toxicity

Embryolarvae studies on one fish species (preferably bluegill), and one aquatic invertebrate life-cycle study (preferably on daphnia) may be required pending the receipt and results of mobility and persistence studies.

Effects on Aquatic Invertebrates

Acute Toxicity

Data on the acute toxicity of dialifor to one species of aquatic invertebrates is required but were not available.

Effects on Estuarine Organisms

Acute Toxicity

Estuarine Invertebrates

The following data were available to assess the acute toxicity of dialifor to estuarine invertebrates:

Species:	Test Substance:	LC50:	Citation:
Grass Shrimp *Palaemonetes vulgaris*	Technical	3.56 ppb (3.02-4.19)	Sleight, 00002191
Mud Crab *Neopanope texana*	Technical	33.5 ppb (23.9-46.9)	Sleight, 00002191

There is sufficient information to characterize dialifor as very highly toxic to estuarine invertebrates. No additional data are required, except to support the registration of products used on citrus. Due to the proximity of citrus crops to estuarine areas, toxicity tests are also required on an estuarine fish (96-hour LC50). In addition, either a 48-hour EC50 embryo-larvae or 96-hour EC50 shell deposition test in molluscs is also required.

Effects on Nontarget Soil and Surface Invertebrates

Acute Oral and Contact Toxicity

Honey bees

The following data were availble to assess the acute oral and contact toxicity of dialifor to honey bees:

Species:	Test Substance:	Results:	Citation:
Honey bee (*Apis mellifera*)	Technical	Oral LD50: 29.2 ug/bee Contact LD50: 9.5-28.6 ug/bee	Stevenson, J.H.; 05001991
Honey bee (*Apis mellifera*)	EC	At 1 lb./100 gal., highly toxic as direct application, low in toxicity as 3 hr. residue	Johansen, C., Eves, J.; 00001949
Honey bee (*Apis mellifera*)	Unk.	Relatively non-toxic Contact LD50: 34.5 ug/bee	Atkins, L., Anderson, L.D.; 00001999

There is sufficient information to characterize dialifor as generally low in toxicity to honey bees except when applied directly to bees as an emulsifiable concentrate. No additional data are required.

Predators and Parasites

The following data were available to assess the toxicity of dialifor to predator species:

Species:	Test Substance:	Results:	Citation:
Lady beetle (*Stethorus punctum*)	6 lb/gallon EC	At .375 lbs. ai per 100 gal., highly toxic to larvae and eggs, moderately toxic to adults and non-toxic to pupae.	Colburn, R., Asquith, D; 05004007
Predatory Mite (*Metaseiulus occidentalis*)	Unknown	Moderately to highly suitable for IPM in grapes.	AliNiazee, M., 05001683

There is sufficient information to characterize dialifor as variable in toxicity to insect predators. Toxicity is variable depending upon species and life stage.

Ecological Effects Profile: Emulsifiable Concentrate Dialifor

The maximum recommended rate (1 lb ai/acre) of dialifor formulated as a 4 pound per gallon emulsifiable concentrate was shown to cause temporary spotting and chlorosis on grapes. A second study tested an unspecified 40% dialifor formulation which is assumed to be the 4 lb per gallon emulsifiable concentrate. This study showed that a 5000 ppm ai aqueous spray of dialifor (equivalent to 4 lb ai/acre) caused no damage to bean, pea, tomato, cucumber, melon, or spinach. A 1000 ppm spray (equivalent to .8 lb ai/acre) caused no damage to the above crops as well as no damage to corn, soybeans, radish, or chinese cabbage. The equivalent rates per acre were calculated from test concentrations assuming an application of 100 gallon of spray per acre.

Ecological Effects Hazard Assessment: Emulsifiable Concentrate Dialifor

A limited plant hazard assessment can be completed for only the plants tested. Grapes can be expected to suffer only temporary phytotoxic injury when exposed to dialifor at the recommended rate. Beans, peas, tomato, cucumber, melon, and spinach should suffer no phytotoxicity when exposed to .8 lb ai/acre, and corn, soybean, radish, and chinese cabbage should suffer no damage at rates up to 4 pounds ai/acre.

Topical Discussions

Effects on Algae, Fungi, and Aquatic Macrophytes

Data were not available on the effects of dialifor on algae, fungi, or aquatic macrophytes. Data are required on the effects of dialifor on growth of aquatic plants (163.122-2).

Effects on Terrestrial Macrophytes

Based on the available data, the following information is known about the toxicity of dialifor to terrestrial macrophytes:

Species	Formulation	No-effect Level	Author/Date	ID#
Grape	4 lb/gallon EC	1 lb. ai/A	Frost-1970	00002069

----------The 1 pound rate caused some leaf spotting and chlorosis, but no------ ----------damage was apparent 3 weeks after treatment.-------------------------

Corn	40%	1000 ppm ai= 8 lb/A	Ishitani-1975	05006342
Soybean	"	1000 ppm ai= 8 lb/A	"	"
Bean	"	5000 ppm ai= 4 lb/A	"	"
Pea	"	5000 ppm ai= 4 lb/A	"	"
Tomato	"	5000 ppm ai= 4 lb/A	"	"
Cucumber	"	5000 ppm ai= 4 lb/A	"	"
Melon	"	5000 ppm ai= 4 lb/A	"	"
Radish	"	1000 ppm ai= 8 lb/A	"	"
Chinese Cabbage	"	1000 ppm ai= 8 lb/A	"	"
Spinach	"	5000 ppm ai= 4 lb/A	"	"

All plants were sprayed with aqueous solutions until thoroughly wet, and rated 1-10 days after treatment. The equivalent rates in pounds per acre were calculated based on use of 100 gallons of spray per acre. Based on the labels of registered dialifor products, this 40% material is probably the 4 lb/gallon emulsifiable concentrate. Testing is required on the effects of dialifor on seed germination/seedling emergence.

No data were available on the wettable powder formulation of dialifor.

IX. CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

    b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Standard

Case: GS:0010 Dialifor

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